Our Docket No.: 99-0120 / 7553.00029

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant:	Stephen J. Brown		
Application No.:	09/237,194	Examiner:	Morgan, R.
Filed:	January 26, 1999	Art Group:	3626
For:	REMOTE HEALTH-MONITORING SYSTEM WITH NETWORKED SERVER AND HEALTH CARE PROFESSIONAL		

APPEAL BRIEF

Mail Stop - Appeal Brief Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellant submits the following Appeal Brief pursuant to 37 C.F.R. §41.37 for consideration by the Board of Patent Appeals and Interferences. Enclosed herewith is the charge $510.00 to cover the cost of filing the opening brief, as required by 37 C.F.R. §41.20(b)(2). Please charge any additional fees or credit any overpayment to Deposit Account Number 50-0541.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real parties in interest are Health Hero Network, Inc:, the assignee of record and a subsidiary of Robert Bosch North America, and Abbott Diabetes Care, a subsidiary of Abbott Laboratories, Inc., a licensee of the application.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to the Appellant, Appellant's legal representative, or Assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-33 have been cancelled. Claims 34-138 are pending and remain rejected. The Appellant hereby appeals the rejection of claims 34-138.

IV. STATUS OF AMENDMENTS

Appellant is appealing a final Office Action issued by the Examiner on August 10, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. In a first embodiment, represented by independent claim 34, the presently claimed invention provides a networked health-monitoring system (e.g., see FIGS. 1 and 11 and page 28, lines 31-36), comprising: (a) a plurality of remote patient sites (e.g., 58 in FIG. 2), each site including (i) at least one display (e.g., 28 in FIG. 1), (ii) a data management unit (e.g., 10 in FIG. 1) configured to facilitate collection of patient health-related data, (iii) a memory (e.g., 41, 42, 43 in FIG. 1; 90, 92, 94 in FIG. 3) and (iv) stored program instructions (e.g., see page 24, lines 7-24) for use in generating health-monitoring related information on the display (e.g., see FIGS. 4-10 and page 10, lines 27-28); (b) at least one remotely located computing facility including at least one central server (e.g., 54 in FIGS. 1 and 2) connectable for communication with the data management units at the patient sites (e.g., see page 15, lines 27-35), the central server configured to receive and store the patient health-related data from the data management unit at the remote patient sites (e.g., see page 16, lines 23-35); and (c) at least one health care professional computer remotely located from and configured for signal communication with the central server (e.g., 62 in FIG. 2), wherein the central server can generate a report based on the patient health-related data collected at the remote patient site (e.g., see page 25, lines 27-32) and the report can be viewed at the at least one healthcare professional computer (e.g., see page 18, lines 23-31 and page 25, lines 27-32) and wherein at least one message can be sent from the healthcare professional computer to the remote patient sites through the central server (e.g., see page 18, lines 23-31 and page 25, lines 27-32).

B. In a second embodiment, represented by independent claim 71, the presently claimed

invention provides a networked health-monitoring system (e.g.,see FIGS. 1 and 11 and page 28, lines 31-36) comprising: (a) a plurality of remote patient sites (e.g., 58 in FIG. 2), each site including (i) at least one display (e.g., 28 in FIG. 1), (ii) a data management unit (e.g., 10 in FIG. 1) configured to facilitate collection of patient health-related data, (iii) a memory (e.g., 41, 42, 43 in FIG. 1; 90, 92, 94 in FIG. 3) and (iv) stored program instructions (e.g., see page 24, lines 7-24) for use in generating health-monitoring related information on the display (e.g., see FIGS. 4-10 and page 10, lines 27-28); (b) at east one remotely located computing facility including at least one central server (e.g., 54 in FIGS. 1 and 2) connectable for communication with the data management units at the patient sites (e.g., see page 15, lines 27-35); and (c) at least one health care professional computer (e.g., 62 in FIG. 2) configured for signal communication with the central server to receive information based on the patient health-related data collected at the remote patient sites (e.g., see page 16, lines 23-35), wherein hardware and software of the central server can communicate with the data management units to enable program instructions to be provided from the server for reconfiguring programs stored at a remote patient site (e.g., see page 15, line 27 through page 16, line 5) and wherein the system is configured to transmit a message for display on at least one remote patient site display (e.g., see page 16, lines 6-22).

C. In a third embodiment, represented by independent claim 76, the presently claimed invention provides a networked health-monitoring system (e.g., see FIGS. 1 and 11 and page 28, lines 31-36) comprising: (a) a plurality of remote patient sites (e.g., 58 in FIG. 2), each site including (i) at least one display (e.g., 28 in FIG. 1), (ii) a plurality of buttons keys or switches (e.g., 30, 32,

34, 36, 38 in FIG. 1), (iii) a data management unit (e.g., 10 in FIG. 1) configured to facilitate collection of patient health-related data, (iv) a memory (e.g., 41, 42, 43 in FIG. 1; 90, 92, 94 in FIG. 3) and (v) stored program instructions (e.g., see page 24, lines 7-24) for use in generating health-monitoring related information on the display (e.g., see FIGS. 4-10 and page 10, lines 27-28) and (b) at least one remotely located computing facility including at least one central server (e.g., 54 in FIGS. 1 and 2) connectable for communication with the data management units at the patient sites (e.g., see page 15, lines 27-35), wherein the central server can generate at least one report (e.g., see page 15, line 27 through page 16, line 5 and page 25, lines 27-32); and at least one health care professional computer (e.g., 62 in FIG. 2) configured for signal communication with the central server to receive at least one report based on the patient health-related data collected at the remote patient sites (e.g., see page 15, line 27 through page 16, line 5 and page 25, lines 27-32), wherein the at least one report is standardized (e.g., see page 15, line 27 through page 16, line 5), and wherein hardware and software of the central server communicates the report to the healthcare professional computer after an authorization code is transmitted to the server to identify an associated healthcare professional as an authorized user (e.g., see page 17, lines 10-30), and wherein reconfiguring program instructions stored in a cartridge are used for reconfiguring the stored program instructions (e.g., page 10, line 6-11).

D. In a fourth embodiment, represented by independent claim 77, the presently claimed invention provides a method of collecting and processing patient health-related data, comprising: (a) at a plurality of remote patient sites (e.g., 58 in FIG. 2), (i) using stored program instructions to

generate health-monitoring related information on at least one display (e.g., see FIGS. 4-10 and page 10, lines 27-28), (ii) facilitating collection of patient health-related data using a data management unit (e.g., 10 in FIG. 1 and page 10, line 32 through page 11, line 30) and (iii) collecting patient-health related data (e.g., see 16, 20 and 22 in FIG. 1 and page 10, line 32 through page 11, line 30); (b) connecting at least one remotely located computing facility including at least one central server for communication with the data management unit at the patient sites (e.g., 54 in FIGS. 1 and 2); and (c) providing at least one report to at least one health care professional computer (e.g., see page 15, line 27 through page 16, line 5), remotely located from and in signal communication with the central server, the report being based on the patient health-related data collected at the remote patient sites, and wherein hardware and software of the central server allows at least one message sent from the health care professional computer to be sent to the remote patient site (e.g., see page 18, lines 23-31 and page 25, lines 27-32).

E. In a fifth embodiment, represented by independent claim 114, the presently claimed invention provides a method of collecting and processing patient heath-related data comprising: (a) at a plurality of remote patient sites (e.g., 58 in FIG. 2), (i) using stored program instructions to generate health-monitoring related information on at least one display (e.g., see FIGS. 4-10 and page 10, lines 27-28), (ii) facilitating collection of patient health-related data using a data management unit (e.g., 10 in FIG. 1 and page 10, line 32 through page 11, line 30) and (iii) collecting patient-health related data (e.g., see 16, 20 and 22 in FIG. 1 and page 10, line 32 through page 11, line 30); (b) connecting at least one remotely located computing facility including at least one central server

for communication with the data management unit at the patient sites (e.g., 54 in FIGS. 1 and 2); (c) providing information based on the patient health-related data collected at the remote patient sites to at least one health care professional computer, remotely located from and in signal communication with the central server (e.g., see page 18, lines 23-31 and page 25, lines 27-32); (d) providing programs from the server to a remote patient site (e.g., see page 22, line 26 through page 23, line 7); and (e) storing in a memory and executing the programs at the remote patient site (e.g., see page 22, line 26 through page 23, line 7).

F. In a sixth embodiment, represented by independent claim 119, the presently claimed invention provides a method of collecting and processing patient health-related data comprising: (a) a plurality of remote patient sites (e.g., 58 in FIG. 2), (i) using stored program instructions to generate health-monitoring related information on at least one display (e.g., see FIGS. 4-10 and page 10, lines 27-28), (ii) facilitating collection of patient health-related data using a data management unit (e.g., 10 in FIG. 1 and page 10, line 32 through page 11, line 30) and (iii) collecting patient-health related data (e.g., see 16, 20 and 22 in FIG. 1 and page 10, line 32 through page 11, line 30); (b) connecting at least one remotely located computing facility including at least one central server for communication with the data management unit at the patient sites (e.g., 54 in FIGS. 1 and 2); (c) providing at least one report to at least one health care professional computer, remotely located from and in signal communication with the central server, the report being based on the patient health-related data collected at the remote patient sites (e.g., see page 18, lines 23-31 and page 25, lines 27-32), wherein hardware and software of the central server allows at least one message to be sent from

the health care professional computer to be sent to the remote patient site (e.g., see page 18, lines 23-31 and page 25, lines 27-32); and (d) receiving the report after transmitting an authorization code to the server that identifies an associated healthcare professional as an authorized user (e.g., see page 17, lines 10-30).

G. In a seventh embodiment, represented by independent claim 120, the presently claimed invention provides a system (e.g., see FIGS. 1, 2 and 11 and page 10, line 19 through page 11, line 30) for collecting and processing patient health-related data comprising: (a) a plurality of remote patient sites (e.g., 58 in FIG. 2), each site including (i) means for using stored program instructions to generate health-monitoring related information at least one display (e.g., see FIGS. 1 and 4-10, page 10, lines 27-28 and page 24, lines 7-24); (ii) means for facilitating collection of patient health-related data using a data management unit (e.g., see FIGS. 1, 2 and 11 and page 10, line 19 through page 11, line 30); (iii) means for connecting at least one remotely located computing facility including at least one central server for communication with the data management units at the patient sites (e.g., 52 in FIG. 1); and (iv) means for providing at least one report to at least one health care professional computer, remotely located from and in signal communication with the central server, the report being based on the patient health-related data collected at the remote patient sites, wherein the report can be viewed at the at least one health care professional computer and at least one message sent from the health care professional computer to the remote patient sites through the central server (e.g., 54 in FIGS. 1 and 2).

H. In an eighth embodiment, represented by independent claim 121, the presently claimed invention provides a networked health-monitoring system (e.g., see FIGS. 1, 2 and 11 and page 10, line 19 through page 11, line 30), comprising: (a) a plurality of remote patient sites (e.g., 58 in FIG. 2), each site including (i) at least one display (e.g., 28 in FIG. 1), (ii) a plurality of buttons, keys or switches (e.g., 30, 32, 34, 36, 38 in FIG. 1), (iii) a data management unit (e.g., 10 in FIG. 1) configured to facilitate collection of patient health-related data using one or more of the plurality of buttons, keys or switches (e.g., see page 10, line 32 through page 12, line 16 and page 13, line 25 through page 14, line 22), (iv) a memory (e.g., 41, 42, 43 in FIG. 1; 90, 92, 94 in FIG. 3) and (v) stored program instructions (e.g., see page 24, lines 7-24) for use in generating health-monitoring related information on the display (e.g., see FIGS. 4-10 and page 10, lines 27-28); (b) at least one remotely located computing facility including at least one central server connectable for communication with the data management units at the patient sites (e.g., 54 in FIGS. 1 and 2); and (c) at least one health care professional computer remotely located from and configured for signal communication with the central server (e.g., 62 in FIG. 2) to receive information based on the patient health-related data collected at the remote patient sites and to send educational or motivational messages to the patient (e.g., see page 7, lines 16-24), wherein hardware and software of the central server automatically communicates with the data management units and the at least one health care professional computer (e.g., see page 20, lines 24-31), and wherein the system is configured to enable a patient at a remote patient site to respond to health-monitoring related information generated on the display by using a cursor or other indicator positioned at an item on the display (e.g., see page 6, line 30 through page 7, line 4).

I. In a ninth embodiment, represented by independent claim 122, the presently claimed invention provides a method of collecting and processing patient health-related data, comprising: (a) a plurality of remote patient sites (e.g., 58 in FIG. 2), (i) using stored program instructions to generate health-monitoring related information on at least one display (e.g., see FIGS. 4-10 and page 10, lines 27-28), (ii) facilitating collection of patient health-related data using a data management unit (e.g., 10 in FIG. 1 and page 10, line 32 through page 11, line 30), and (iii) collecting patient-health related data (e.g., see 16, 20 and 22 in FIG. 1 and page 10, line 32 through page 11, line 30); (b) connecting at least one remotely located computing facility including at least one central server for communication with the data management unit at the patient sites (e.g., 54 in FIGS. 1 and 2); (c) providing information, based on the patient health-related data collected at the remote patient sites, to at least one health care professional computer remotely located from the central server (e.g., see page 18, lines 23-31 and page 25, lines 27-32); (d) enabling a patient at a remote patient site to respond to health-monitoring related information generated on the display by using a cursor or other indicator positioned at an item on the display (e.g., see page 6, line 30 through page 7, line 4); and (e) sending educational or motivational messages to the remote patient sites (e.g., see page 7, lines 16-24).

J. In a tenth embodiment, represented by independent claim 123, the presently claimed invention provides a networked health-monitoring system (e.g., see FIGS.1, 2 and 11 and page 28, lines 31-36), comprising: (a) a plurality of remote patient sites (e.g., 58 in FIG. 2), each site including (i) at least one display (e.g., 28 in FIG. 1), (ii) a data management unit (e.g., 10 in FIG. 1) configured

to facilitate collection of patient health-related data, (iii) a memory (e.g., 41, 42, 43 in FIG. 1; 90, 92, 94 in FIG. 3) and (iv) stored program instructions (e.g., see page 24, lines 7-24) for use in generating health-monitoring related information on the display (e.g., see FIGS. 4-10 and page 10, lines 27-28); (b) at least one remotely located computing facility including at least one central server connectable for communication with the data management units at the patient sites (e.g., 54 in FIGS. 1 and 2); and (c) at least one healthcare professional computer remotely located from and configured for signal communication with the central server to receive at least one report based on the patient health-related data collected at the remote patient sites (e.g., 62 in FIG. 2), wherein hardware and software of the central server (i) are configured to receive and store health-related data from a remote patient site (e.g., see page 16, lines 23-35), and to generate a report that can be viewed or retrieved by an authorized user from the remotely located healthcare professional computer (e.g., page 17, lines 10-30), and wherein the central server receives and stores messages from the remotely located professional computer and transmits them to the data management unit for presentation to the patient display (e.g., page 18, lines 23-31), (ii) can communicate with the data management units to enable program instructions to be provided from the server for reconfiguring programs stored at a remote patient site (e.g., page 10, line 6-11), and (iii) send educational or motivational messages to the patient (e.g., see page 7, lines 16-24).

K. In an eleventh embodiment, represented by independent claim 124, the presently claimed invention provides a method of collecting and processing patient health-related data, comprising: (a) at a plurality of remote patient sites (e.g., 58 in FIG. 2), (i) using stored program

instructions to generate health-monitoring related information on at least one display (e.g., see FIGS. 4-10, page 10, lines 27-28 and page 24, lines 7-24), (ii) facilitating collection of patient health-related data using a data management unit (e.g., 10 in FIG. 1 and page 10, line 32 through page 11, line 30), and (iii) collecting patient-health related data (e.g., see 16, 20 and 22 in FIG. 1 and page 10, line 32 through page 11, line 30); (b) connecting at least one remotely located computing facility including at least one central server for communication with the data management unit at the patient sites (see FIG. 2), wherein the central server generates at least one report (e.g., see page 17, lines 10-30); and (c) providing the at least one report to at least one health care professional computer, remotely located from and in signal communication with the central server, the report being based on the patient health-related data collected at the remote patient sites (e.g., see page 18, lines 23-31 and page 25, lines 27-32), wherein hardware and software of the central server (i) are configured to receive and store health-related data from a remote patient site (e.g., see page 16, lines 23-35), and to generate a report that can be viewed or retrieved by an authorized user from the remotely located healthcare professional computer (e.g., see page 17, lines 10-30), and wherein the central server receives and stores messages from the remotely located professional computer and transmits them to the data management unit for presentation to the patient display (e.g., see page 18, lines 23-31), (ii) can communicate with the data management units to enable program instructions to be provided from the server for reconfiguring programs stored at a remote patient site (e.g., see page 10, lines 23-31), and (iii) send educational or motivational messages to the patient (e.g., see page 7, lines 16-24).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The first ground of rejection to be reviewed is whether claims 34-41, 45-50, 52, 54-59, 61-63, 66, 69-75, 77-84, 88-93, 95, 97-102, 104-106, 108, 109 and 112-118 are patentable under 35 U.S.C. §103 over Fu et al.[1] and Lee[2] in view of Kirk et al.[3]

The second ground of rejection to be reviewed is whether claims 42, 44, 85 and 87 are patentable under 35 U.S.C. §103 over Fu, Lee and Kirk and further in view of Beckers.[4]

The third ground of rejection is whether claims 51, 53, 60, 64, 67, 68, 94,96, 103, 107, 110 and 111 are patentable under 35 U.S.C. §103 over Fu, Lee and Kirk and further in view of Fujimoto.[5]

The fourth ground of rejection to be reviewed is whether claims 43 and 86 are patentable under 35 U.S.C. §103 over Fu, Lee and Kirk, and further in view of the Examiner's use of Official Notice.

The fifth ground of rejection to be reviewed is whether claims 76 and 119-138 are patentable under 35 U.S.C. §103 over Fu, Lee and Kirk, and further in view of Examiner's use of Official Notice.

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[1] U.S. Patent No. 4,803,625; hereinafter Fu.

[2] U.S. Patent No. 4,838,275.

[3] U.S. Patent No. 5,390,238; hereinafter Kirk.

[4] U.S. Patent No. 5,019,974.

[5] U.S. Patent No. 5,339,821.

VII. ARGUMENTS

A. 35 U.S.C. §103

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.[6] If the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of non-obviousness.[7] An Applicant may overcome a 35 U.S.C. §103 rejection based on a combination of references by showing completion of the invention by the Applicant prior to the effective date of any of the references.[8] The Applicant need not antedate the reference with the earliest filing date.[9] The Applicant may antedate a reference by providing evidence of prior conception of the invention coupled with reasonable diligence beginning prior to the effective reference date until either an actual reduction to practice of the invention or the filing of the patent application.[10] Proof of reasonable diligence does not require the inventor to work constantly on the invention or to drop all other work.[11]

As explained below, the Appellant has provided evidence of prior conception of the present invention coupled with reasonable diligence beginning prior to the effective date of Kirk et

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[6] Manual of Patent Examining Procedure (M.P.E.P.), Eighth Edition, Revision 6, September 2007, §2142.

[7] M.P.E.P. §2142.

[8] M.P.E.P. §715.02(I).

[9] M.P.E.P. §715.02(I).

[10] See 37 CFR 1.131(b).

[11] *Mycogen Plant Science, Inc., v. Monsanto Co.*, 252 F.3d 1306, 1316, 58 USPQ2d 1891, 1899 (Fed. Cir. 2001), reh'g denied, 261 F.3d 1345, 59 USPQ2d 1852 (Fed. Cir. 2001); see *Bey v. Kollonitsch*, 806 F.2d 1024, 1028, 231 USPQ 967, 970 (Fed. Cir. 1986).

al.[12] until the effective filing date of the present patent application.[13] Since all of the 35 U.S.C. §103 rejections are based on combinations with the Kirk reference, the rejections should be reversed.

1. Claims 34-41, 45-50, 52, 54-59, 61-63, 66, 69-75, 77-84, 88-93, 95, 97-102, 104-106, 108, 109 and 112-118 are patentable under 35 U.S.C. §103 over Fu and Lee in view of Kirk.

As set forth on page 2 of the final Office Action,[14] claims 34-41, 45-50, 52, 54-59, 61-63, 66, 69-75, 77-84, 88-93, 95, 97-102, 104-106, 108, 109 and 112-118 are rejected under 35 U.S.C. §103(a) as being unpatentable over Fu and Lee in view of Kirk.

Appellant may overcome the rejection under 35 U.S.C. §103 based on the combination of Fu, Lee and Kirk references by showing completion of the invention by the Applicant prior to the effective date of any of the references.[15] Appellant may antedate a reference by providing evidence of prior conception of the invention coupled with reasonable diligence beginning prior to the effective reference date until either an actual reduction to practice of the invention or the filing of the patent application.[16] The earliest priority date of Kirk is June 15, 1992. In particular, Kirk has

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[12] U.S. Patent No. 5,390,238; hereinafter Kirk.

[13] See Declaration of Stephen J Brown Pursuant to 37 C.F.R. §1.131 ("Declaration of Stephen J Brown"), filed September 19, 2006, and associated exhibits included in the Evidence Appendix.

[14] Dated August 10, 2007.

[15] M.P.E.P. §715.02(I).

[16] See 37 CFR 1.131(b).

a filing date of June 15, 1992.[17] The present invention was conceived prior to June 15, 1992.[18] Specifically, paragraphs 7 and 8 of the Declaration of Stephen J. Brown state that the present invention was conceived prior to June 15, 1992 and point how material described in Exhibit B, a fax letter dated March 2, 1992, corresponds to the elements in FIG. 1 of the present patent application. Thus, Appellant has provided evidence of conception prior to June 15, 1992. Therefore, the earliest effective filing date of Kirk is after the conception of the present invention.

Contrary to the position taken by the Examiner,[19] Appellant has provided specific evidence that he worked reasonably diligently from prior to June 15, 1992 until November 17, 1992, the effective filing date of the present application. In particular, the Declaration of Stephen J. Brown and the associated Exhibits A-AB, which were filed on September 19, 2006, provide specific evidence of reasonable diligence from just prior to the filing date of Kirk (i.e., June 15, 1992) up to the effective filing date of the present application (i.e., November 17, 1992). The presently claimed invention was conceived prior to the effective date of Kirk and diligently reduced to practice through the filing of the patent application to which the present application claims priority. Therefore, Kirk is not available as prior art against the claims. As such, the presently pending claims are fully patentable over the cited references and the rejection should be reversed.

The Examiner cites the MPEP §2138.06 as stating "The work relied upon to show

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[17] See Kirk at page 1, item (22).

[18] See paragraph 7 of the Declaration of Stephen J. Brown, filed September 19, 2006.

[19] See page 3, section 8 of the final Office Action dated August 10, 2007.

reasonable diligence must be directly related to the reduction to practice of the invention in issue."[20] The Declaration of Stephen J. Brown[21] clearly identifies how the work evidenced by the associated exhibits is directly related to the development of technology for the presently claimed invention. For example, paragraph 2 of the Declaration of Stephen J. Brown[22] identifies how work evidenced by the attached exhibits was related to development of the elements of the presently claimed invention. Paragraphs 14, 15, 18, 19 and 21-28 of the Declaration of Stephen J. Brown[23] also identify exhibits providing evidence of ongoing work related to the reduction to practice of the present invention.

The Examiner further cites the MPEP §2138.06 as stating that "The period during which diligence is required must be accounted for by either affirmative acts or acceptable excuses."[24] However, proof of reasonable diligence does not require the inventor to work constantly on the invention or to drop all other work.[25] The Declaration of Stephen J. Brown[26] clearly identifies both affirmative acts and acceptable excuses accounting for the period during which diligence is required.

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[20] See page 4, lines 14-17, of the final Office Action dated August 10, 2007, citing MPEP §2138.06.

[21] Filed September 19, 2006.

[22] Filed September 19, 2006.

[23] Filed September 19, 2006.

[24] See page 4, lines 6-13, of the final Office Action dated August 10, 2007, citing MPEP §2138.06.

[25] *Mycogen Plant Science, Inc., v. Monsanto Co.*, 252 F.3d 1306, 1316, 58 USPQ2d 1891, 1899 (Fed. Cir. 2001), reh'g denied, 261 F.3d 1345, 59 USPQ2d 1852 (Fed. Cir. 2001); see *Bey v. Kollonitsch*, 806 F.2d 1024, 1028, 231 USPQ 967, 970 (Fed. Cir. 1986).

[26] Filed September 19, 2006.

For example, paragraph 9 of the Declaration of Stephen J. Brown[27] states that the Appellant was the Chief Executive Officer (CEO) of the start-up company Raya Systems, Inc. Paragraph 10 of the of the Declaration of Stephen J. Brown[28] further states:

> During the period from March 2, 1992 to November 17, 1992, I was either diligently working on the present invention, or performing my other duties as CEO of the company. The time line has been detailed with various documents attached as Exhibits C to AB, which are described below.

Paragraphs 11-32 an 35-46 of the Declaration of Stephen J. Brown[29] and the referenced exhibits account for affirmative acts either taken in furtherance of the present invention or related to Appellant's duties as CEO.

The Examiner further cites the MPEP §2138.06 as stating that "An applicant must account for the entire period during which diligence is required (citing Gould v. Schawlow)" and "Diligence requires that applicant must be specific as to dates and facts."[30] The Declaration of Stephen J. Brown[31] clearly identifies work accounting for the entire period from prior to the filing date of Kirk (i.e., June 15, 1992) up to the effective filing date of the present application (i.e., November 17, 1992). Furthermore, the of the Declaration of Stephen J. Brown[32] does not merely

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[27] Filed September 19, 2006.

[28] Filed September 19, 2006.

[29] Filed September 19, 2006.

[30] See page 4, lines 1-5, of the final Office Action dated August 10, 2007, citing MPEP §2138.06.

[31] Filed September 19, 2006.

[32] Filed September 19, 2006.

state that there were no weeks or months that the invention was not worked on.[33] Rather, the Declaration of Stephen J. Brown[34] and the associated exhibits are specific with regard to dates and facts. Therefore, the Appellant has presented evidence accounting for the entire period during which reasonable diligence is required.

Furthermore, the Examiner's statement that the exhibits describe only a patient interface system but have no integration of the overall system including a physician interface until Exhibit T dated August 13, 1992, does not appear to recognize that the efforts taken by the Appellant need not be the most expeditious, but rather it is enough that the efforts taken lead to a reduction to practice.[35] Specifically, MPEP §2138.06 states:

> Although it is possible that patentee could have reduced the invention to practice in a shorter time by relying on stock items rather than by designing a particular piece of hardware, patentee exercised reasonable diligence to secure the required hardware to actually reduce the invention to practice. "[I]n deciding the question of diligence it is immaterial that the inventor may not have taken the expeditious course....".[36]

In the case of the present invention as in the case of *Justus*, it is immaterial to the question of reasonable diligence that the exhibits have no integration of the overall system including a physician interface until Exhibit T dated August 13, 1992.

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[33] See M.P.E.P. §2138.06, citing Gould v. Schawlow, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966) for the proposition that "Merely stating that there were no weeks or months that the invention was not worked on is not enough."

[34] Filed September 19, 2006.

[35] See M.P.E.P. §2138.06, citing Justus v. Appenzeller.

[36] MPEP §2138.06, citing Justus v. Appenzeller, 177 USPQ 332, 340-1 (Bd. Pat. Inter. 1971).

Furthermore, the Declaration of Stephen J. Brown[37] sets forth facts to support that the efforts made were part of an overall scheme of inventive activity directed toward reducing the invention to practice. In *In re Jolley*,[38] the Federal Circuit found that the PTO Board did not err in determining that it was reasonable for a party to test a simpler composition (e.g., X and Z) as a step toward reducing a more complex composition (e.g., X+Y+Z) to practice. Here as in Jolley, the Appellant's efforts on individual parts of the claimed invention prior to the integration of the individual parts is reasonable and therefore supports that Appellant was reasonably diligent from prior to the filing date of Kirk (i.e., June 15, 1992) up to the effective filing date of the present application (i.e., November 17, 1992).

Furthermore, the conclusion by the Examiner that "the Applicant has failed to provide evidence with respect to works directly related to the reduction to practice of the invention and providing an acceptable excuse for the time lapse between months showing reasonable due diligence"[39] again appears to indicate that the proper standard for reasonable diligence has not been applied. In particular, MPEP §2138.06 states:

> The diligence of 35 U.S.C. 102(g) relates to reasonable "attorney-diligence" and "engineering-diligence" which does not require that "an inventor or his attorney drop all other work and concentrate on the particular invention involved".[40]

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[37] Filed September 19, 2006.

[38] 308 F.3d 1317, 64 USPQ2d 1901 (Fed. Cir. 2002).

[39] See last line on page 4 through line 3 on page 5 of the final Office Action dated August 10, 2007.

[40] MPEP §2138.06, citing Keizer v. Bradley, 270 F.2d 396, 397, 123 USPQ 215, 216 (CCPA 1959) and Emery v. Ronden, 188 USPQ 264, 268 (Bd. Pat. Inter. 1974).

The fact that the Appellant need not drop everything and work only on the invention is further evidenced by the Federal Circuit's decision in Monsanto Co. v. Mycogen Plant Science, Inc.[41] In Monsanto, the Court stated:

> The law regarding diligence is settled.
>
> ***
>
> However, there need not necessarily be evidence of activity on every single day if a satisfactory explanation is evidenced. Proof of reasonable diligence, however, does not require a party to work constantly on the invention or to drop all other work [citing Mycogen Plant Science, Inc. v. Monsanto Co., 252 F.3d 1306, 1316, 58 USPQ2d 1891, 1899 (Fed. Cir. 2001)].

The Declaration of Stephen J. Brown[42] clearly provides satisfactory explanations to excuse a requirement for evidence of activity on every single day. Specifically, paragraph 10 of the Declaration of Stephen J. Brown[43] states:

> During the period from March 2, 1992 to November 17, 1992, I was either diligently working on the present invention, or performing my other duties as CEO of the company. The time line has been detailed with various documents attached as Exhibits C to AB, which are described below.

Paragraph 11 of the Declaration of Stephen J. Brown[44] states:

> My duties as CEO included preparing applications for grants, which directly contributed to financing needed to develop and produce products related to the present invention, traveling, attending

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[41] 261 F.3d 1356, 59 USPQ2d 1930 (Fed. Cir. 2001); hereinafter Monsanto.

[42] Filed September 19, 2006.

[43] Filed September 19, 2006.

[44] Filed September 19, 2006.

> conferences, as well as other items related to the day to day running of the company. As is common for most CEOs, I worked hours far in excess of the normal 40 hour week.

Paragraphs 11-32 and 35-46 of the Declaration of Stephen J. Brown[45] and the referenced exhibits account for affirmative acts taken in furtherance of the present invention or related to Appellant's duties as CEO. Paragraphs 33 and 34 of the Declaration of Stephen J. Brown[46] account for time when Appellant was with his family. Paragraph 29 of the Declaration of Stephen J. Brown[47] and Exhibit Q provide evidence of the employment of an individual during the period from June 1992 to December 1992 whose work included development of the present invention. Thus, Appellant has submitted evidence showing that work toward reducing the invention to practice was ongoing and providing satisfactory explanations to excuse a requirement for proof that activity took place on every single day.

Furthermore, in Monsanto the Court cited Jones v. Evans[48] as finding diligence despite a possible interval from April 16 to early in July in which it did not affirmatively appear that any steps were being taken, but during which some activity was ongoing. The Declaration of Stephen J. Brown[49] and associated exhibits clearly evidence that activity on the present invention was ongoing during the period from prior to the filing date of Kirk (i.e., June 15, 1992) up to the effective

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[45] Filed September 19, 2006.

[46] Filed September 19, 2006.

[47] Filed September 19, 2006.

[48] 46 F.2d 197, 202, 8 USPQ 240, 245 (1931).

[49] Filed September 19, 2006.

filing date of the present application (i.e., November 17, 1992). Furthermore, the full time employment of Jack Thornton as Director of Product Development during the period from June 1992 through December 1992 and the fact that his job included working on the specifications for the present invention[50] provide evidence that activity on the present invention was ongoing during the period from prior to the filing date of Kirk (i.e., June 15, 1992) up to the effective filing date of the present application (i.e., November 17, 1992). Therefore, here, as in Jones v. Evans, the Declaration of Stephen J. Brown[51] and associated exhibits factually support that Appellant was reasonably diligent from prior to the filing date of Kirk (i.e., June 15, 1992) up to the effective filing date of the present application (i.e., November 17, 1992).

Furthermore, the Examiner's statement that "the Exhibits have at least 2 days of inactivity and the Applicant has not providing [sic] an acceptable excuse in order to account for time lapse between these lapses" appears to be an indirect reference to In re Mulder,[52] cited in M.P.E.P. §2138.06 as a case where "a 2-day period lacking activity has been held to be fatal."[53] However, Mulder is not applicable to the present case. Specifically, in Mulder, the Court stated:

> A liberal construction of [Rule 131], which is clearly intended to benefit applicants, will permit applicants to show diligence from just prior to the date of the reference to their convention filing date, rather than all the way from their proven conception date, but liberality cannot be extended to the point of eliminating all proof of diligence,

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[50] See paragraph 20 of the Declaration of Stephen J. Brown and Exhibit Q, filed September 19, 2006.

[51] Filed September 19, 2006.

[52] 716 F.2d 1542, 219 USPQ 189 (Fed. Cir. 1983).

[53] See M.P.E.P. §2138.06, citing In re Mulder.

> no matter how short the period to be covered. Appellants' difficulty, as they have had to admit, is that there is no evidence whatever of record showing diligence, and therefore they cannot comply with the rule. Focusing on the shortness of the gap is misleading. During the period between the time the draft application was received in this country and the time the application was filed in the U.S. PTO, the record shows no activity of any kind in this country. . . . Under the circumstances, the PTO's refusal to accept the declarations as meeting the requirements of Rule 131 must be affirmed because of the total lack of evidence of diligence to couple conception to the filing date--leaving a hiatus--and Rodgers must be treated as prior art.[54]

The record in the present case, unlike in Mulder, clearly shows activity occurring from prior to the filing date of Kirk (i.e., June 15, 1992) up to the effective filing date of the present application (i.e., November 17, 1992). Thus, unlike in Mulder, the present record does not suffer from a total lack of evidence of diligence to couple the prior conception of the present invention from prior to the filing date of Kirk (i.e., June 15, 1992) up to the effective filing date of the present application (i.e., November 17, 1992).. Thus, in contrast to Mulder, the Declaration of Stephen J. Brown[55] and the associated exhibits factually support that Appellant was reasonably diligent from prior to the filing date of Kirk (i.e., June 15, 1992) up to the effective filing date of the present application (i.e., November 17, 1992). Therefore, Kirk is not available as prior art against the claims. As such, the combination of Fu, Lee and Kirk is not proper and the rejection should be reversed.

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[54] 716 F.2d at 1545, 219 USPQ at 193.

[55] Filed September 19, 2006.

2. Claims 42, 44, 85 and 87 are patentable under 35 U.S.C. §103 over Fu, Lee and Kirk and further in view of Beckers.

As set forth on page 2 of the final Office Action,[56] claims 42, 44, 85 and 87 are rejected under 35 U.S.C. §103(a) as being unpatentable over Fu, Lee and Kirk, and further in view of Beckers.

Because the rejection under 35 U.S.C. §103(a) of claims 42, 44, 85 and 87 is based upon a combination with Kirk, the arguments presented above in Section 1 are hereby incorporated by reference to support reversal of the rejection under 35 U.S.C. §103(a) of claims 42, 44, 85 and 87. For the reasons presented in Section 1 above, Kirk is not available as prior art against the claims. As such, the combination of Fu, Lee, Kirk and Beckers is not proper and the rejection should be reversed.

3. Claims 51, 53, 60, 64, 67, 68, 94,96, 103, 107, 110 and 111 are patentable under 35 U.S.C. §103 over Fu, Lee and Kirk and further in view of Fujimoto.

As set forth on page 2 of the final Office Action,[57] claims 51, 53, 60, 64, 67, 68, 94,96, 103, 107, 110 and 111 are rejected under 35 U.S.C. §103(a) as being unpatentable over Fu, Lee and Kirk, and further in view of Fujimoto.

Because the rejection under 35 U.S.C. §103(a) of claims 51, 53, 60, 64, 67, 68, 94,96,

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[56] Dated August 10, 2007.

[57] Dated August 10, 2007.

103, 107, 110 and 111 is based upon a combination with Kirk, the arguments presented above in Section 1 are hereby incorporated by reference to support reversal of the rejection under 35 U.S.C. §103(a) of claims 51, 53, 60, 64, 67, 68, 94,96, 103, 107, 110 and 111. For the reasons presented in Section 1 above, Kirk is not available as prior art against the claims. As such, the combination of Fu, Lee, Kirk and Fujimoto is not proper and the rejection should be reversed.

4. Claims 43 and 86 are patentable under 35 U.S.C. §103 over Fu, Lee and Kirk, and further in view of the Examiner's use of Official Notice.

As set forth on page 3 of the final Office Action,[58] claims 43 and 86 are rejected under 35 U.S.C. §103(a) as being unpatentable over Fu, Lee and Kirk, and further in view of the Examiner's use of Official Notice.

Because the rejection under 35 U.S.C. §103(a) of claims 43 and 86 is based upon a combination with Kirk, the arguments presented above in Section 1 are hereby incorporated by reference to support reversal of the rejection under 35 U.S.C. §103(a) of claims 43 and 86. For the reasons presented in Section 1 above, Kirk is not available as prior art against the claims. As such, the combination of Fu, Lee, Kirk with the Examiner's use of Official Notice is not proper and the rejection should be reversed.

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[58] Dated August 10, 2007.

5. Claims 76 and 119-138 are patentable under 35 U.S.C. §103 over Fu, Lee and Kirk, and further in view of Examiner's use of Official Notice.

As set forth on page 3 of the final Office Action,[59] claims 76 and 119-138 are rejected under 35 U.S.C. §103(a) as being unpatentable over Fu, Lee and Kirk, and further in view of the Examiner's use of Official Notice.

Because the rejection under 35 U.S.C. §103(a) of claims 76 and 119-138 is based upon a combination with Kirk, the arguments presented above in Section 1 are hereby incorporated by reference to support reversal of the rejection under 35 U.S.C. §103(a) of claims 76 and 119-138. For the reasons presented in Section 1 above, Kirk is not available as prior art against the claims. As such, the combination of Fu, Lee, Kirk with the Examiner's use of Official Notice is not proper and the rejection should be reversed.

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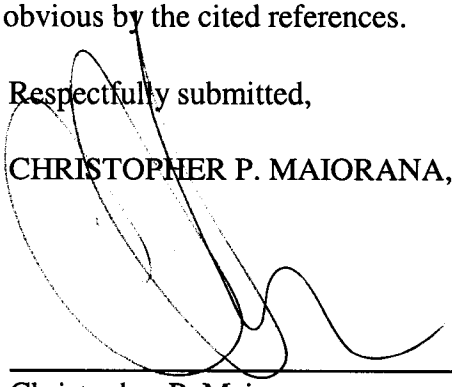
[59] Dated August 10, 2007.

B. CONCLUSION

Appellant has provided specific evidence of prior conception coupled with reasonable diligence from prior to June 15, 1992, the effective filing date of Kirk, until November 17, 1992, the effective filing date of the present application. In particular, the Declaration of Stephen J. Brown and the associated Exhibits A-AB, which were filed on September 19, 2006, provide specific evidence of reasonable diligence from just prior to the filing date of Kirk (i.e., June 15, 1992) up to the effective filing date of the present application (i.e., November 17, 1992). The presently claimed invention was conceived prior to the effective date of Kirk and diligently reduced to practice through the filing of the patent application to which the present application claims priority. Hence, the Examiner has clearly erred with respect to the patentability of the claimed invention. It is respectfully requested that the Board overturn the Examiner's rejections of all pending claims, and hold that the claims are not rendered obvious by the cited references.

Respectfully submitted,

CHRISTOPHER P. MAIORANA, P.C.



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Dated: March 31, 2008

c/o Sandeep Jaggi
Health Hero Network

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VIII. CLAIM APPENDIX

The claims of the present application which are involved in this appeal are as follows:

Claims 1-33 (CANCELLED).

34. (PREVIOUSLY PRESENTED) A networked health-monitoring system, comprising:

(a) a plurality of remote patient sites, each site including

(i) at least one display;

(ii) a data management unit configured to facilitate collection of patient health-related data;

(iii) a memory; and

(iv) stored program instructions for use in generating health-monitoring related information on the display;

(b) at least one remotely located computing facility including at least one central server connectable for communication with the data management units at the patient sites, the central server configured to receive and store the patient health-related data from the data management unit at the remote patient sites; and

(c) at least one health care professional computer remotely located from and configured for signal communication with the central server,

wherein the central server can generate a report based on the patient health-related data collected at the remote patient site and the report can be viewed at the at least one healthcare

professional computer and wherein at least one message can be sent from the healthcare professional computer to the remote patient sites through the central server.

35. (PREVIOUSLY PRESENTED) The system of claim 121, further comprising at least one health-monitoring device configured

(a) to monitor at least one patient health condition at least one remote patient site; and

(b) to communicate data related to the monitored condition to the central server.

36. (PREVIOUSLY PRESENTED) The system of claim 35, wherein the data management unit facilitates collection of health-related data by receiving data related to the monitored condition from at least one of the health-monitoring devices.

37. (PREVIOUSLY PRESENTED) The system of claim 36, wherein at least one health-monitoring device includes one or more of the set consisting of

(a) a blood glucose monitor;

(b) a peak flow meter;

(c) a blood pressure monitor;

(d) pulse monitor; and

(e) a body temperature monitor.

38. (PREVIOUSLY PRESENTED) The system of claim 66, wherein the data management unit is configured to facilitate collection of health-related data through a patient at the remote patient site using buttons, keys or switches.

39. (PREVIOUSLY PRESENTED) The system of claim 35, wherein the data management unit is physically separate from the display.

40. (PREVIOUSLY PRESENTED) The system of claim 35, wherein the display forms a part of at least one of the health-monitoring devices.

41. (PREVIOUSLY PRESENTED) The system of claim 121, wherein the display is in a handheld device.

42. (PREVIOUSLY PRESENTED) The system of claim 41, wherein the handheld device is capable of displaying pictorial health-monitoring related information.

43. (PREVIOUSLY PRESENTED) The system of claim 40, wherein the memory is a program cartridge.

44. (PREVIOUSLY PRESENTED) The system of claim 41, wherein the handheld device is capable of displaying animated health-monitoring related information.

45. (PREVIOUSLY PRESENTED) The system of claim 121, wherein at least one of the remote sites further includes at least one personal computer and wherein the data management unit at that site is connectable to the computer.

46. (PREVIOUSLY PRESENTED) The system of claim 121, wherein the information received by the healthcare professional can be used to generate at least one report that is standardized.

47. (PREVIOUSLY PRESENTED) The system of claim 76, wherein the system is configured to allow a health care professional to select which of a plurality of standardized reports is received.

48. (PREVIOUSLY PRESENTED) The system of claim 76, wherein the report includes at least one of graphs and icons.

49. (PREVIOUSLY PRESENTED) The system of claim 76, wherein the report can be generated periodically.

50. (PREVIOUSLY PRESENTED) The system of claim 48, wherein the server can generate the report.

51. (PREVIOUSLY PRESENTED) The system of claim 76, wherein the system is configured to cause the presentation of at least one report on the display at a remote patient site.

52. (PREVIOUSLY PRESENTED) The system of claim 76, wherein the report includes displayed formatted statistical information.

53. (PREVIOUSLY PRESENTED) The system of claim 52, wherein the statistical information can be displayed on a display at a remote patient site.

54. (PREVIOUSLY PRESENTED) The system of claim 76, wherein the report includes information data for a period of time.

55. (PREVIOUSLY PRESENTED) The system of claim 121, wherein the system is configured to transmit a message for display on at least one remote patient site display.

56. (PREVIOUSLY PRESENTED) The system of claim 71, wherein the message includes step-by-step instructions.

57. (PREVIOUSLY PRESENTED) The system of claim 71, wherein the message includes results of a test.

58. (PREVIOUSLY PRESENTED) The system of claim 71, wherein the message includes a diagnostic indication related to whether a test has proceeded in a normal fashion.

59. (PREVIOUSLY PRESENTED) The system of claim 71, wherein the message is a multi-line message.

60. (PREVIOUSLY PRESENTED) The system of claim 71, wherein the message is educational or motivational.

61. (PREVIOUSLY PRESENTED) The system of claim 71, wherein the message is from the health care professional computer.

62. (PREVIOUSLY PRESENTED) The system of claim 61, wherein the system is configured to cause the message to be transmitted to a specific patient at a patient site.

63. (PREVIOUSLY PRESENTED) The system of claim 62, wherein the system is configured to cause the message to be transmitted automatically to the patient.

64. (PREVIOUSLY PRESENTED) The system of claim 62, wherein the system enables the patient to choose when to receive the message.

65. (PREVIOUSLY PRESENTED) The system of claim 62, wherein the message is stored before being transmitted to the patient.

66. (PREVIOUSLY PRESENTED) The system of claim 7l, wherein the system is configured to allow a patient at a patient site to control the display of health-monitoring related information using at least one menu.

67. (PREVIOUSLY PRESENTED) The system of claim 66, wherein the menu allows the patient to select anyone of the operational modes from the set consisting of:

(a) a display mode for displaying relevant information;

(b) an input mode for providing information; and

(c) a communications mode for establishing a link with the central server.

68. (PREVIOUSLY PRESENTED) The system of claim 66, wherein the menu allows a patient to select a monitoring mode in which at least one of the health-monitoring devices is used.

69. (PREVIOUSLY PRESENTED) The system of claim 66, wherein the menu allows a patient to display at least one message or instruction from a health care professional.

70. (PREVIOUSLY PRESENTED) The system of claim 69, wherein the system

is configured to enable the patient to respond to information on the display by using a cursor or other indicator positioned at a selected item.

71. (PREVIOUSLY PRESENTED) A networked health-monitoring system comprising:

(a) a plurality of remote patient sites, each site including

(i) at least one display;

(ii) a data management unit configured to facilitate collection of patient health-related data;

(iii) a memory; and

(iv) stored program instructions for use in generating health-monitoring related information on the display;

(b) at east one remotely located computing facility including at least one central server connectable for communication with the data management units at the patient sites; and

(c) at least one health care professional computer configured for signal communication with the central server to receive information based on the patient health-related data collected at the remote patient sites,

wherein hardware and software of the central server can communicate with the data management units to enable program instructions to be provided from the server for reconfiguring programs stored at a remote patient site; and

wherein the system is configured to transmit a message for display on at least one remote

patient site display.

72. (PREVIOUSLY PRESENTED) The system of claim, 121, wherein the collected patient health-related data includes indications of user-experienced symptoms.

73. (PREVIOUSLY PRESENTED) The system of claim, 121, wherein the collected patient health-related data includes quantitative measurements.

74. (PREVIOUSLY PRESENTED) The system of claim 73, wherein the collected patient health-related data includes medication data.

75. (PREVIOUSLY PRESENTED) The system of claim 73, wherein the collected patient \ health-related data includes time data.

76. (PREVIOUSLY PRESENTED) A networked health-monitoring system comprising:

(a) a plurality of remote patient sites, each site including

(i) at least one display;

(ii) a plurality of buttons keys or switches

(iii) a data management unit configured to facilitate collection of patient health-related data;

(iv) a memory; and

(v) stored program instructions for use in generating health-monitoring related information on the display; and

(b) at least one remotely located computing facility including at least one central server connectable for communication with the data management units at the patient sites, wherein the central server can generate at least one report; and at least one health care professional computer configured for signal communication with the central server to receive at least one report based on the patient health-related data collected at the remote patient sites,

wherein the at least one report is standardized, and

wherein hardware and software of the central server communicates the report to the healthcare professional computer after an authorization code is transmitted to the server to identify an associated healthcare professional as an authorized user, and

wherein reconfiguring program instructions stored in a cartridge are used for reconfiguring the stored program instructions.

77. (PREVIOUSLY PRESENTED) A method of collecting and processing patient health-related data, comprising:

(a) at a plurality of remote patient sites,

(i) using stored program instructions to generate health-monitoring related information on at least one display;

(ii) facilitating collection of patient health-related data using a data management unit;

and

(iii) collecting patient-health related data;

(b) connecting at least one remotely located computing facility including at least one central server for communication with the data management unit at the patient sites; and

(c) providing at least one report to at least one health care professional computer, remotely located from and in signal communication with the central server, the report being based on the patient health-related data collected at the remote patient sites, and

wherein hardware and software of the central server allows at least one message sent from the health care professional computer to be sent to the remote patient site.

78. (PREVIOUSLY PRESENTED) The method of claim 122, further comprising using at least one health-monitoring device to

(i) monitor at least one patient health condition at least one remote patient site; and

(ii) communicate data related to the monitored condition to the central server.

79. (PREVIOUSLY PRESENTED) The method of claim 78, wherein the data management unit facilitates collection of health-related data by receiving data related to the monitored condition from at least one of the health-monitoring devices.

80. (PREVIOUSLY PRESENTED) The method of claim 79, wherein at least one health-monitoring device includes one or more of the set consisting of

(a) a blood glucose monitor;

(b) a peak flow meter;

(c) a blood pressure monitor;

(d) a pulse monitor; and

(e) a body temperature monitor.

81. (PREVIOUSLY PRESENTED) The method of claim 109, wherein the data management unit facilitates collection of health-related data entered by a patient at the remote patient site using buttons, keys or switches.

82. (PREVIOUSLY PRESENTED) The method of claim 78, wherein the data management unit is physically separate from the display.

83. (PREVIOUSLY PRESENTED) The method of claim 78, wherein the display form a part of at least one of the health-monitoring devices.

84. (PREVIOUSLY PRESENTED) The method of claim 122, wherein the display is in a handheld device.

85. (PREVIOUSLY PRESENTED) The method of claim 84, wherein the memory is a program cartridge.

86. (PREVIOUSLY PRESENTED) The method of claim 83, further comprising displaying pictorial health-monitoring related information on the handheld device.

87. (PREVIOUSLY PRESENTED) The method of claim 44, further comprising displaying animated health-monitoring related information on the handheld device.

88. (PREVIOUSLY PRESENTED) The method of claim 122, further comprising connecting at least one personal computer to the data management unit at least one remote site.

89. (PREVIOUSLY PRESENTED) The method of claim 77, wherein the information received by the healthcare professional can be used to generate at least one report that is standardized.

90. (PREVIOUSLY PRESENTED) The method of claim 119, wherein a health care professional selects which of a plurality of standardized reports is received.

91. (PREVIOUSLY PRESENTED) The method of claim 119, wherein the report includes at least one of graphs and icons.

92. (PREVIOUSLY PRESENTED) The method of claim 119, wherein the report is generated periodically.

93. (PREVIOUSLY PRESENTED) The method of claim 89, wherein the server generates the report.

94. (PREVIOUSLY PRESENTED) The method of claim 119, further comprising presenting at least one report on a display at a remote patient site.

95. (PREVIOUSLY PRESENTED) The method of claim 119, wherein the report includes statistical information.

96. (PREVIOUSLY PRESENTED) The method of claim 119, further comprising displaying the statistical information on a display at a remote patient site.

97. (PREVIOUSLY PRESENTED) The method of claim 119, wherein the report includes information data for a period of time.

98. (PREVIOUSLY PRESENTED) The method of claim 122, further comprising transmitting at least one message to and displaying it on at least one remote patient site display.

99. (PREVIOUSLY PRESENTED) The method of claim 114, wherein the message includes step-by-step instructions.

100. (PREVIOUSLY PRESENTED) The method of claim 114, wherein the message includes results of a test.

101. (PREVIOUSLY PRESENTED) The method of claim 100, wherein the message includes diagnostic an indication related to whether a test has proceeded in a normal fashion.

102. (PREVIOUSLY PRESENTED) The system of claim, 114, wherein the message is a multi-line message.

103. (PREVIOUSLY PRESENTED) The method of claim 114, wherein the message is educational or motivational.

104. (PREVIOUSLY PRESENTED) The method of claim 114, wherein the message is from the health care professional computer.

105. (PREVIOUSLY PRESENTED) The method of claim 114, wherein the message is transmitted to a specific patient site.

106. (PREVIOUSLY PRESENTED) The method of claim 105, wherein the message is transmitted automatically to the patient.

107. (PREVIOUSLY PRESENTED) The method of claim 105, wherein the patient chooses when to receive the message.

108. (PREVIOUSLY PRESENTED) The method of claim 105, wherein the message is stored before being transmitted to the patient.

109. (PREVIOUSLY PRESENTED) The method of claim 114, wherein a patient at a patient site controls the display of health-monitoring related information using at least one menu.

110. (PREVIOUSLY PRESENTED) The method of claim 109, wherein the menu allows a patient to select anyone of the operational modes from the set consisting of:

(a) a display mode for displaying relevant information;

(b) an input mode for providing information; and

(c) a communications mode for establishing a link with the central server.

111. (PREVIOUSLY PRESENTED) The method of claim 109, wherein the menu allows a patient to select a monitoring mode in which at least one of the health-monitoring devices is used.

112. (PREVIOUSLY PRESENTED) The method of claim 109, wherein the menu allows a patient to display at least one message or instructions from a health care professional.

113. (PREVIOUSLY PRESENTED) The method of claim 112, wherein the patient responds to information on the display by using a cursor or other indicator positioned at a selected item.

114. (PREVIOUSLY PRESENTED) A method of collecting and processing patient heath-related data comprising:

(a) at a plurality of remote patient sites,

(i) using stored program instructions to generate health-monitoring related information on at least one display;

(ii) facilitating collection of patient health-related data using a data management unit; and

(iii) collecting patient-health related data

(b) connecting at least one remotely located computing facility including at least one central server for communication with the data management unit at the patient sites;

(c) providing information based on the patient health-related data collected at the remote patient sites to at least one health care professional computer, remotely located from and in signal communication with the central server;

(d) providing programs from the server to a remote patient site; and

(e) storing in a memory and executing the programs at the remote patient site.

115. (PREVIOUSLY PRESENTED) The method of claim 122 wherein the

collected patient health-related data includes indications of user-experienced symptoms.

116. (PREVIOUSLY PRESENTED) The method of claim 122, wherein the collected patient health-related data includes quantitative measurements.

117. (PREVIOUSLY PRESENTED) The method of claim 122, wherein the collected patient health-related data includes medication data.

118. (PREVIOUSLY PRESENTED) The system of claim 122, wherein the collected patient health-related date includes time data.

119. (PREVIOUSLY PRESENTED) A method of collecting and processing patient health-related data comprising:

(a) a plurality of remote patient sites,

(i) using stored program instructions to generate health-monitoring related information on at least one display;

(ii) facilitating collection of patient health-related data using a data management unit; and

(iii) collecting patient-health related data;

(b) connecting at least one remotely located computing facility including at least one central server for communication with the data management unit at the patient sites;

(c) providing at least one report to at least one health care professional computer, remotely located from and in signal communication with the central server, the report being based on the patient health-related data collected at the remote patient sites,

wherein hardware and software of the central server allows at least one message to be sent from the health care professional computer to be sent to the remote patient site, and

(d) receiving the report after transmitting an authorization code to the server that identifies an associated healthcare professional as an authorized user.

120. (PREVIOUSLY PRESENTED) A system for collecting and processing patient health-related data comprising:

(a) a plurality of remote patient sites, each site including

(i) means for using stored program instructions to generate health-monitoring related information at least one display;

(ii) means for facilitating collection of patient health-related data using a data management unit;

(iii) means for connecting at least one remotely located computing facility including at least one central server for communication with the data management units at the patient sites; and

(iv) means for providing at least one report to at least one health care professional computer, remotely located from and in signal communication with the central server, the report being based on the patient health-related data collected at the remote patient sites,

wherein the report can be viewed at the at least one health care professional computer and

at least one message sent from the health care professional computer to the remote patient sites through the central server.

121. (PREVIOUSLY PRESENTED) A networked health-monitoring system, comprising:

(a) a plurality of remote patient sites, each site including

(i) at least one display;

(ii) a plurality of buttons, keys or switches

(iii) a data management unit configured to facilitate collection of patient health-related data using one or more of the plurality of buttons, keys or switches;

(iv) a memory; and

(v) stored program instructions for use in generating health-monitoring related information on the display;

(b) at least one remotely located computing facility including at least one central server connectable for communication with the data management units at the patient sites; and

(c) at least one health care professional computer remotely located from and configured for signal communication with the central server to receive information based on the patient health-related data collected at the remote patient sites and to send educational or motivational messages to the patient,

wherein hardware and software of the central server automatically communicates with the data management units and the at least one health care professional computer; and

wherein the system is configured to enable a patient at a remote patient site to respond to health-monitoring related information generated on the display by using a cursor or other indicator positioned at an item on the display.

122. (PREVIOUSLY AMENDED) A method of collecting and processing patient health-related data, comprising:

(a) a plurality of remote patient sites,

(i) using stored program instructions to generate health-monitoring related information on at least one display;

(ii) facilitating collection of patient health-related data using a data management unit; and

(iii) collecting patient-health related data;

(b) connecting at least one remotely located computing facility including at least one central server for communication with the data management unit at the patient sites;

(c) providing information, based on the patient health-related data collected at the remote patient sites, to at least one health care professional computer remotely located from the central server;

(d) enabling a patient at a remote patient site to respond to health-monitoring related information generated on the display by using a cursor or other indicator positioned at an item on the display; and

(e) sending educational or motivational messages to the remote patient sites.

123. (PREVIOUSLY PRESENTED) A networked health-monitoring system, comprising:

(a) a plurality of remote patient sites, each site including

(i) at least one display;

(ii) a data management unit configured to facilitate collection of patient health-related data;

(iii) a memory; and

(iv) stored program instructions for use in generating health-monitoring related information on the display;

(b) at least one remotely located computing facility including at least one central server connectable for communication with the data management units at the patient sites; and

(c) at least one healthcare professional computer remotely located from and configured for signal communication with the central server to receive at least one report based on the patient health-related data collected at the remote patient sites,

wherein hardware and software of the central server

(i) are configured to receive and store health-related data from a remote patient site, and to generate a report that can be viewed or retrieved by an authorized user from the remotely located healthcare professional computer, and wherein the central server receives and stores messages from the remotely located professional computer and transmits them to the data management unit for presentation to the patient display,

(ii) can communicate with the data management units to enable program instructions to be provided from the server for reconfiguring programs stored at a remote patient site, and

(iii) send educational or motivational messages to the patient.

124. (PREVIOUSLY PRESENTED) A method of collecting and processing patient health-related data, comprising:

(a) at a plurality of remote patient sites,

(i) using stored program instructions to generate health-monitoring related information on at least one display;

(ii) facilitating collection of patient health-related data using a data management unit; and

(iii) collecting patient-health related data;

(b) connecting at least one remotely located computing facility including at least one central server for communication with the data management unit at the patient sites, wherein the central server generates at least one report; and

(c) providing the at least one report to at least one health care professional computer, remotely located from and in signal communication with the central server, the report being based on the patient health-related data collected at the remote patient sites, wherein hardware and software of the central server

(i) are configured to receive and store health-related data from a remote patient site, and to generate a report that can be viewed or retrieved by an authorized user from the remotely

located healthcare professional computer, and wherein the central server receives and stores messages from the remotely located professional computer and transmits them to the data
20 management unit for presentation to the patient display,

(ii) can communicate with the data management units to enable program instructions to be provided from the server for reconfiguring programs stored at a remote patient site, and

(iii) send educational or motivational messages to the patient.

125. (PREVIOUSLY PRESENTED) The system of claim 71, wherein the program instructions for reconfiguring programs effect changes in a treatment regimen, effect changes in analyses or reports generated by the by the system, or effect changes in graphical presentations of the system.

126. (PREVIOUSLY PRESENTED) The system of claim 76, wherein the program instructions for reconfiguring programs effect changes in a treatment regimen, effect changes in analyses or reports generated by the by the system, or effect changes in graphical presentations of the system.

127. (PREVIOUSLY PRESENTED) The method of claim 114, wherein the program instructions for reconfiguring programs effect changes in a treatment regimen, effect changes in analyses or reports generated by the by the system, or effect changes in graphical presentations of the system.

128. (PREVIOUSLY PRESENTED) The system of claim 34, wherein the patient health-related data includes raw data.

129. (PREVIOUSLY PRESENTED) The system of claim 128, wherein raw data includes test results and related data.

130. (PREVIOUSLY PRESENTED) The system of claim 128, wherein the patient health-related data includes symptomatic information.

131. (PREVIOUSLY PRESENTED) The system of claim 34, wherein the patient health-related data includes test results and related data.

132. (PREVIOUSLY PRESENTED) The system of claim 131, wherein the test results and related data are stored in the memory.

133. (PREVIOUSLY PRESENTED) The system of claim 132, wherein the memory is in the data management unit.

134. (PREVIOUSLY PRESENTED) The system of claim 76, wherein the additional program instructions are communicated to the remote patient site and the remotely located

computing facility.

135. (PREVIOUSLY PRESENTED) The system of claim 134, wherein the additional program instructions are communicated to the cartridge through the central server.

136. (PREVIOUSLY PRESENTED) The method of claim 114, wherein the programs provided from the server to a remote patient site can be stored and executed at the remote patient site.

137. (PREVIOUSLY PRESENTED) The method of claim 136, wherein the programs provided from the server to a remote patient site reconfigure existing programs stored at the remote patient site.

138. (PREVIOUSLY PRESENTED) The system of claim 76, wherein the reconfiguring program instructions are stored in the cartridge and the cartridge can be returned to the remote patient site.

IX. EVIDENCE APPENDIX

A. Declaration of Stephen J. Brown Pursuant to 37 C.F.R. §1.131 and accompanying Exhibits A-AB, filed September 21, 2006, entered on record as of September 21, 2006.

B. Declaration/Affidavit of Prior Invention in the United States to Overcome Cited Patent or Publication (37 C.F.R. §1.131) and accompanying Exhibits 1-10, filed July 6, 2004, entered on the record as of July 6, 2004.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Stephen J. Brown		
Assignee:	Health Hero Network		
Title:	REMOTE HEALTH-MONITORING SYSTEM WITH NETWORKED SERVER AND HEALTH CARE PROFESSIONAL		
Serial No.:	09/237,194	Filed:	January 26, 1999
Examiner:	Morgan, R.	Art Unit:	3626
Attorney Docket No.:	99-0120 / 7553.00029		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF STEPHEN J. BROWN PURSUANT TO 37 C.F.R. S 1.131

I, Stephen J. Brown, hereby declare as follows:

1. I am the sole inventor of the subject matter claimed in the above-identified patent application U.S. Serial Number 09/237,194.

2. The various exhibits that will be referenced in this document relate to the claim elements of the pending claims. In particular, certain documents will relate to the remote patient sites (e.g., patient interface), certain documents will relate to the central server (e.g., database), and certain documents will relate to the health care provider computer (e.g., provider interface). Each of the three main elements had considerable amounts of work in

development that were undertaken. References to the blood glucose meter, and the project Camit EL, the project Nintendo, the project KinderCamit Software, each relate to the patient interface element. Documents relating to Diabcare relate to development of the database element. Documents related to Camit S relate to development of the provider interface. The individual modules were worked on as stand alone elements to develop technologies to be integrated as the system of the present invention. The strategy to integrate the technologies developed through the individual projects was kept confidential.

3. The Nintendo, Diabcare, and Camit S projects were developing modules and system elements that at the time functioned as stand alone products. Diabcare and Camit were modules sold as stand alone systems to Boehringer Mannheim GmbH. The Nintendo projects included diabetes and psychological assessment (attention deficit disorder) modules that were developed in part under Small Business Innovation Research grants from the National Institutes of Health. The diabetes module was sold to Novo Nordisk Pharmaceuticals Inc, Novo Nordisk A/S and to PCSL Software Ireland Ltd. We pursued these projects in order to create technologies and software that we could integrate as a complete modular micro-processor-based health monitoring system, with Nintendo-based patient interface, a network database, and a provider interface for data analysis, as described in my letter of March 2.

4. The above-identified patent application is a continuation of prior U.S. application U.S.S.N. 08/481,925, filed June 7, 1995, now U.S.P.N. 5,899,855, which is a continuation of prior U.S. application U.S.S.N 08/233,397, filed April 26, 1994, now abandoned, which is a

continuation-in-part of prior U.S. application U.S.S.N. 07/977,323, filed November 17, 1992, now U.S.P.N. 5,307,263 (see item 1 on page 1 of the transmittal letter attached as part of Exhibit A and the domestic priority information table on page 2 of the supplemental application data sheet attached as part of Exhibit A).

5. The above-identified patent application claims priority to the filing date (i.e., November 17, 1992) of U.S.P.N. 5,307,263 under 35 U.S.C. §120 (see item 1 on page 1 of the transmittal letter attached as Exhibit A).

6. The effective filing date of U.S. Patent No. 5,390,238 (Kirk et al.) is the date that Kirk et al. is effective as a reference under 35 U.S.C. § 102(e), i.e., June 15, 1992.

7. Prior to June 15, 1992, I conceived the invention claimed in the above-identified patent application as shown by the fax letter from me to Boerhringer Mannheim GmbH attached as Exhibit B. The fax letter of Exhibit B shows an original document date of March 2, 1992.

8. The third paragraph of the fax letter attached as Exhibit B describes elements which correspond to those in FIG. 1 of the present patent application. For example, the data management program corresponds to the data management unit 10, the Nintendo video game corresponds to the handheld unit 12, the modem mentioned for connecting a home system to a doctor system corresponds to the modem 52. The statement that the system described in the fax letter could be an ideal platform for a home system which connects to the doctor

system via modem corresponds with the communications with doctors at 52 and the fact that the doctor and patient are remote from each other (implicit in the words "home system which connects to the doctor").

9. During the period from March 2, 1992 to November 17, 1992, I was the Chief Executive Officer (CEO) of a start-up company, Raya Systems, Inc.

10. During the period from March 2, 1992 to November 17, 1992, I was either diligently working on the present invention, or performing my other duties as CEO of the company. The time line has been detailed with various documents attached as Exhibits C to AB, which are described below.

11. My duties as CEO included preparing applications for grants, which directly contributed to financing needed to develop and produce products related to the present invention, traveling, attending conferences, as well as other items related to the day to day running of the company. As is common for most CEOs, I worked hours far in excess of the normal 40 hour week.

12. On or around March 5, 1992, I indicated to the National Institutes of Health (NIH) that Raya Systems was completing a research plan and intended to prepare an application for Phase II funding (see letter to Dr. Charles Wells attached as pages 1-2 of Exhibit C). The research plan was funded by an NIH grant awarded in response to a grant application I submitted

under the Small Business Innovation and Research (SBIR) program for a project entitled "Computer Game for Diabetes Education" (see grant application and Notice of Award attached as pages 3-7 of Exhibit C). The performance period for the research plan ran from September 5, 1991 through March 5, 1992. After completion of the research plan, I was responsible for writing and submitting a final report on the Diabetes grant.

13. In addition to the Diabetes project, I and others at Raya Systems worked on various interactive patient self-care education and self-monitoring projects supported by Small Business Innovation and Research grants from the National Institutes of Health. I was the principal investigator and dedicated a portion of my time to managing these projects which were related to developing the patient interface for diabetes and several other conditions. One of these conditions was the Attention Deficit Disorder grant, which was a patient interface related project in which we were developing subjective data collection measures from interactive patient software on a Nintendo video game system. I was obligated to spend 25% of my time as principle investigator between March 10, 1992 and September 9, 1992 (see grant application and Notice of Grant Award attached as pages 8-11 of Exhibit C).

14. On or before March 18, 1992, a preliminary design document for KinderCamit was generated as shown by the copy of the design document attached as Exhibit D. The KinderCamit document relates to development of the patient interface portion of the present invention.

15. On March 25, 1992, I received a draft letter to review from Richard Black. A redacted copy of the letter is attached as Exhibit E. The letter concerned negotiations for an exclusive license from video game manufacture Nintendo which was being sought. The license being sought related to the development of the patient interface portion of the present invention.

16. From March 28, 1992 to April 13, 1992, I was involved in preparing the Phase II grant application and soliciting consultants and advisors for the project.

17. On April 13, 1992, the grant application was submitted.

18. A copy of an invoice from Oles, Morrison and Rinker for legal services from March 23, 1992 through April 22, 1992 is attached as Exhibit F. The invoice is dated May 13, 1992 and shows the time spent on March 24, 1992 and on March 25, 1992 in preparation of the letter to Nintendo attached as Exhibit E and, therefore, relates to the development of the patient interface. The invoice also shows that on April 20, 1992, April 21, 1992 and April 22, 1992 I spent time on company business.

19. A fax letter dated May 11, 1992 from Todd Raming to Hartmut Kassulke which includes a time table for development of Camit S 2.5 is attached as Exhibit G. The letter relates to activity pertaining to the development on the provider interface.

20. A copy of a fax, including a Speaker Release Form, from me to Amy Philips dated May 12, 1992 and a letter from Linda Cann to me dated May 4, 1992 is attached as Exhibit H. The fax was sent in preparation for me presenting at the 52nd Annual Scientific Sessions of the American Diabetes Association.

21. A copy of an invoice from Oles, Morrison and Rinker for legal services from April 23, 1992 through May 22, 1992 is attached as Exhibit I. The invoice in Exhibit I is dated June 10, 1992. The invoice shows activity on May 5, 1992, from May 12, 1992 through May 13, 1992, on May 15, 1992, and from May 20, 1992 through May 21, 1992 regarding a contract with Sculptured Software; Inc. The activity related to development of interactive patient self-care education software that would be part of the patient interface portion of the present invention.

22. A copy of a fax letter from me to Hartmut Kassulke dated May 31, 1992 is attached as Exhibit J. The fax includes a letter dated June 1, 1992, which included a status report on the ongoing development of Camit S 2.5 and Diabcare. The letter shows activity related to the database and provider interface portions of the present invention.

23. A copy of a company meeting agenda, dated June 1, 1992, showing employees and projects is attached as Exhibit K. The agenda lists the Nintendo project which was related to the patient interface portion of the present invention.

24. A copy of a fax letter from Jay Clark to me dated June 2, 1992 is attached as Exhibit L. The fax involved an agreement for hiring Jay Clark as a developer. The hiring of Jay Clark related to development of the interactive patient self-care education software that would be part of the patient interface portion of the present invention.

25. A copy of a letter from George Metos, President of Sculptured Software, Incorporated to me dated June 8, 1992 is attached as Exhibit M. The letter concerns employment of a software developer which related to development of interactive patient self-care education software that would be part of the patient interface portion of the present invention.

26. A redacted copy of a letter from me to Dr. Norbert Jersch dated June 16, 1992, is attached as Exhibit N. The letter included a status report concerning the Diabcare project which was related to activity in the development of the database portion of the present invention.

27. A copy of a letter from me to Dr. Klaus Piwernetz dated June 18, 1992, is attached as Exhibit O. The letter relates to activity on the Diabcare project which was related to activity in the development of the database portion of the present invention.

28. A copy of an invoice from Oles, Morrison and Rinker for legal services provided from May 26, 1992 through June 22, 1992 is attached as Exhibit P. The invoice is dated July 28, 1992 and shows time spent on developer contracts, contracts with Nintendo and confidentiality

agreements which relate to development of the patient interface portion of the present invention.

29. A letter to me from Jeffrey P. Brunner of Emerson Brooks and Associates dated June 25, 1992, a redacted copy of a payroll register for June 1992 and a redacted copy of an employee master information payroll record for 1992 are attached as Exhibit Q. Pay amounts and personal identification numbers have been redacted to preserve the privacy of the employee information. The letter to Jeffrey P. Brunner shows that the company agreed to pay Emerson Brooks for the recruitment of Jack Thornton as software development manager. Jack Thornton was hired as Director of Product Development in June 1992. His work included working on the specifications for the present invention. The payroll register (page 4 of 5) shows Jack Thornton was payed as a full time employee during June of 1992. The employee master information payroll record (page 5 of 5) shows Jack Thornton was payed as a full time employee during June through December 1992. The payroll amounts for Jack Thornton contained in (i) the payroll register (page 4 of 5 of Exhibit Q) and (ii) the employee master information payroll record (page 5 of 5 of Exhibit Q), which are redacted, showed that the same amount was payed for each of the months June through December.

30. A copy of a fax of building plans dated June 25, 1992 and a fax letter from Ed Iglesias of Hansen Bros. to Raya Systems dated July 7, 1992 are attached as Exhibit R. The building plans and letter concern moving plans for Raya Systems with which I was involved. The move took place over a period from about mid July, 1992 through about mid August, 1992.

31. On or around July 1, 1992, I traveled to Dublin, Ireland to meet with PCSL Software Ireland LTD, a company with which Raya Systems was doing business and which was interested in funding a series of patient education programs.

32. Copies of letters from Liz Becker of Novo Nordisk A/S to me, dated July 2, 1992 and July 10, 1992, and a letter from me to Liz Becker dated July 14, 1992 are attached as Exhibit S. The letters attached as Exhibit S show discussion and preparation for me, as CEO of Raya Systems, to attend an EASD conference. Although I was unable to attend the EASD conference, I traveled to Copenhagen, Denmark for a meeting with Novo Nordisk A/S, a company with which Raya Systems was doing business, on or around August 21, 1992.

33. On August 7-8, 1992, I was at my sister's wedding in Wenatchee, Washington.

34. From August 10-15, 1992, I was at a family reunion in Deer Valley Ranch, Colorado.

35. On or before August 13, 1992 enough design work had been done to produce a schematic, a list of features, a hardware wish list and a basic hardware design for the present invention, as well as to hire a hardware engineer, Craig Nelson, as a consultant to implement the invention (see the schematic, list of features, hardware wish list, hand-written notes, hardware description and non disclosure agreement of Craig Nelson attached as Exhibit T).

36. All of the documents in Exhibit T were sent on August 14, 1992 to Richard Black at the law firm of Oles, Morrison & Rinker for the preparation of the patent application filed November 17, 1992 (see the copy of Jack Thornton's fax cover sheet and accompanying documents that were sent to Richard Black attached as Exhibit U).

37. A copy of handwritten notes from me to Jack Thornton dated August 21, 1992 are attached as Exhibit V. The notes were faxed from Copenhagen where I was meeting with Novo Nordisk. The notes relate to continuing development of the present invention.

38. By September 3, 1992 attorney Jim Anable had been instructed to prepare the above-identified patent application (see Richard Black's letter dated September 3, 1992 attached as page 1 of Exhibit W).

39. On September 9, 1992, the NIH indicated that our Phase II proposal was being reviewed and requested further information. A copy of the letter from the NIH requesting further information is attached as pages 1-3 of Exhibit X.

40. From September 11, 1992 through September 16, 1992, we worked on responding to the NIH requests for more information regarding our Phase II grant application. A copy of the letter from me to the NIH responding to the request for further information is attached as pages 4-6 of Exhibit X.

41. A retainer was paid to attorney Jim Anable's firm, Christensen O'Conner, et al., on or around September 15, 1992 (see copy of letter and check attached as pages 2-3 of Exhibit W).

42. On September 30, 1992, the NIH issued a Notice of Grant Award and the performance period began for our Phase II project. A copy of the Notice of Grant Award from the NIH is attached as pages 7-10 of Exhibit X.

43. Attorney Anable sent a first draft of the above-identified patent application to me for review on October 2, 1992 (a copy of the fax cover sheet, pages 1 to 28 of the draft application and the set of figures which were provided to me are attached as Exhibit Y).

44. On October 2, 1992, I faxed, to Jim Anable, a drawing to be included in the application. A copy of the fax cover sheet and the drawing are attached as Exhibit Z.

45. From October 2, 1992 to November 17, 1992, Christensen O'Conner et al. continued to work on the application until the filing of the application on November 17, 1992 (see Christensen O'Conner et al. billing statements dated October 31, 1992 and November 30, 1992 attached as Exhibit AA).

46. The patent application to which the present application claims priority was filed in the United States Patent and Trademark Office on November 17, 1992 as indicated by the Filing Date shown on the Official Filing Receipt attached as Exhibit AB.

47. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or patents issued therefrom.

Date: September, 19, 2006

Stephen J. Brown

G:\HealthHero7553\00029\Declaration 1.131.wpd

C625 U.S. PTO
01/26/99

APPLICATIC

jc542 U.S. PTO
09/237194
01/26/99

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. HERO113397

TRANSMITTAL LETTER

Seattle, Washington 98101

January 26, 1999

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Transmitted herewith for filing under 37 C.F.R. § 1.53(b) by Express Mail is the

__X__ a. complete

_____ b. incomplete

patent application of: Stephen J. Brown,

Title: MODULAR MICROPROCESSOR-BASED HEALTH MONITORING SYSTEM

__X__ 1. This application is a continuation of prior application No. 08/481,925, filed June 7, 1995, which is a continuation of prior application No. 08/233,397, filed April 26, 1994, now abandoned, which is a continuation-in-part of prior application No. 07/977,323, filed November 17, 1992 now U.S. Patent No. 5,307,263, priority from the filing date of which is hereby claimed under 35 U.S.C. § 120.

__X__ 2. An application consisting of 35 pages of specification and claims and 6 sheets of formal drawings is attached.

__X__ 3. A copy of the Declaration and Power of Attorney filed in the above noted prior application is attached.

__X__ i. The entire disclosure of the prior application, from which a copy of the declaration is supplied, is considered as being part of the disclosure of this application and is hereby incorporated by reference herein.

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON & KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
(206) 682-8100

X 4. The prior application was assigned to Raya Systems, Inc., by an assignment recorded at reel 6976/frame 0623, a copy of which is attached. Raya Systems, Inc. has changed its name to Health Hero Network, Inc.

X 5. A copy of the Certificate of Change of Name to Health Hero Network, Inc. is attached.

X 6. A filing date in accordance with 37 C.F.R. § 1.10 is requested. The Express Mail Certificate appears below.

X 7. A Small Entity Statement was filed in the prior application. Small entity status is still proper and desired in this application.

X 7a. A Preliminary Amendment will be filed within the next three months.

COMPUTATION OF FEE

	Number Filed		Number Extra		Rate		Basic Rate $380.00
Total Claims	19 - 20	=	0	x	$9	=	$0.00
Independent Claims	2 - 3	=	0	x	$39	=	$0.00
Multiple Dependent Claims	0		---		$130	=	$0.00
	TOTAL						$380.00

X 8. Our check No. 102820 in the amount of $380.00 to cover the total fee as computed above is enclosed.

X 9. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.18 which may be required during the entire pendency of the application, or credit any overpayment, to Deposit Account No. 03-1740. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire prosecution of this application. A copy of this sheet is enclosed.

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Please address all further correspondence to:

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Respectfully submitted,

CHRISTENSEN O'CONNOR
JOHNSON & KINDNESS PLLC

Richard T. Black

Richard T. Black
Registration No. 40,514
Direct Dial (206) 695-1724

EXPRESS MAIL CERTIFICATE

"Express Mail" mailing label number EM605200668US
Date of Deposit January 26, 1999
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Scott Michaelis
(Typed or printed name of person mailing paper or fee)

Scott Michaelis
(Signature of person mailing paper or fee)

RTB:kh

Supplemental Application Data Sheet

Application Information

Application number::	09/237194
Filing Date::	01/26/99
Application Type::	Regular
Subject Matter::	Utility
Suggested Group Art Unit::	3626
CD-ROM or CD-R?::	None
Sequence submission?::	None
Computer Readable Form (CRF)?::	No
Title::	MODULAR MICROPROCESSOR-BASED HEALTH MONITORING SYSTEM
Attorney Docket Number::	014030.0110N2US
Request for Early Publication?::	No
Request for Non-Publication?::	No
Small Entity?::	No
Petition included?::	No
Secrecy Order in Parent Appl.?::	No

Applicant Information

Applicant Authority Type::	Inventor
Status::	Full Capacity
Given Name::	Stephen
Middle Name::	James
Family Name::	Brown
Street of mailing address::	2570 West El Camino Real Suite 111
City of mailing address::	Mountain View
State or Province of mailing address::	CA
Postal or Zip Code of mailing address::	94040

Correspondence Information

Correspondence Customer Number:: 32042

Representative Information

Representative Customer Number:: 32042

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
09/237,194	Continuation of	08/481,925	06/07/95
08/481,925	Continuation of	08/233,397	04/26/94
08/233,397	Continuation-in-part of	07/977,323	11/17/92

Foreign Priority Information

Assignee Information

Assignee name::	Health Hero Network, Inc.
Street of mailing address::	2570 West El Camino Real
	Suite 111
City of mailing address::	Mountain View
State or Province of mailing address::	CA
Postal or Zip Code of mailing address::	94040

Date March 2, 1992

To ✓Dr. Norbert Jersch
✓Dr. Thomas Keiser
Central Marketing Patient Systems
Boehringer Mannheim GmbH
fax (011 49 621) 759 4179

From Steve Brown
Raya Systems
Mountain View, CA
fax (415) 949 3935

re Camit, Diabcare

Thank you for the order for Camit 2.5. We accept the conditions, except that we would like to start development on April 6, rather than March 1. As I discussed with Hartmut, it makes more sense for us start closer to the time when a prototype will be available. I want to devote continuous attention to the project until completion, rather than doing some development now and then waiting for the prototype EL.

With regard to Diabcare, I would like to have a new agreement confirming our fax transmittals of the last two months.

I have developed an interface for the Camit EL to a Nintendo video game machine, and am producing a data management program for the Super Nintendo Entertainment System. In the United States, Nintendo video game computers are in 40 million homes. They are inexpensive and attach to television sets. Raya Systems is licensed by Nintendo to produce such a product, and I hope to discuss the possibilities with BM USA. Can you tell me who to contact there? This could be an ideal platform for a home system which connects to the doctor system (Camit) via modem.

Sincerely,

Steve Brown

March 5, 1992

Reference: 1 R43 DK44402-01

Dr. Charles Wells
Director, Diabetes Research Program
National Institute of Diabetes and Digestive and Kidney Diseases
Division of Diabetes, Endocrinology and Metabolic Diseases
National Institutes of Health, Westood Building Room 622
5333 Westbard Avenue
Bethesda, MD 20892

Dear Dr. Wells:

We are just finishing our Phase I SBIR project, "Computer Game For Diabetes Education," and we are preparing to apply for Phase II before the April 15 closing date. In Phase I, we modified and evaluated a prototype game we had developed, and designed a Nintendo game which we intended to develop and study in Phase II. In Phase III, we hoped to commercialize the game by working with a corporate sponsor.

As I mentioned on the phone, I have found a corporate sponsor to fund the development and production of a first version of a Nintendo game based on our design and results from Phase I. Although it seems that we have already made it to Phase III with only Phase I funding, important research remains to be done, and I hope to apply for Phase II funding.

I would like to do a longer term controlled study with the educational Nintendo game in patients' homes. We will develop the game cartridges to record some measures internally, give the game cartridges to patients, and then collect them two months later to determine which aspects of our design were the most effective. We will test subjects before and after the two month period and compare results to a control group who received a Nintendo game unrelated to diabetes. A longer term study also allows us to use clinical measures such as glycosylated hemoglobin.

We have already demonstrated that a video game is a feasible approach for diabetes education. It only remains to focus the game on its strongest points, and then develop a full blown, entertainment quality Nintendo game which could be an important teaching and motivational tool for children with diabetes.

My question to you is: Given our situation, is it still appropriate for us to apply for Phase II funding? Important research remains to be done, and will not occur without this funding. We have, however, already begun to commercialize the product. I understand that developing a commercial product is the intent of the SBIR program, but it is not clear to me at which phase this process may begin. I believe we are now in a better position to do a more powerful study, and that an NIDDK grant can be used more efficiently to evaluate and further develop the educational aspects of a Nintendo game designed to teach children about diabetes, because a corporate sponsor has already covered some of the costs of developing such a game.

Sincerely,

Steve Brown
President
Raya Systems, Inc.

OMB No. 0925-0195
Expiration Date 12/31/90

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

SMALL BUSINESS INNOVATION RESEARCH PROGRAM
PHASE I GRANT APPLICATION

FOLLOW INSTRUCTIONS CAREFULLY

LEAVE BLANK		
TYPE	ACTIVITY	NUMBER
REVIEW GROUP		FORMERLY
COUNCIL/BOARD *(Month/year)*		DATE RECEIVED

1. TITLE OF APPLICATION *(Do not exceed 56 typewriter spaces)*
Computer Game for Diabetes Education

2. SBIR SOLICITATION NO. **PHS 90-2**

3. PRINCIPAL INVESTIGATOR ☒ New Investigator

3a. NAME *(Last, first, middle)*
Brown, Stephen James

3b. SOCIAL SECURITY NO.
539-66-5116

3c. POSITION TITLE
President
Raya Systems, Incorporated

3d. MAILING ADDRESS *(Street, city, state, zip code)*
2570 West El Camino Real
Suite 309
Mountain View, California 94040

3e. TELEPHONE *(Area code, number and extension)*
(415) 949-3933

4. HUMAN SUBJECTS ☐NO ☒YES ☒Exemption # 1,2,3 OR ☐Form HHS 596 enclosed

5. VERTEBRATE ANIMALS ☒NO ☐YES

6. DATES OF PROJECT PERIOD
From: 7/1/91 *Through:* 12/31/91

7. COSTS REQUESTED
7a. Direct Costs $ 41,200
7b. Total Costs $ 49,200

8. PERFORMANCE SITES *(Organizations and addresses)*
Stanford University Medical Center
Department of Pediatrics
Stanford, California 94305

Raya Systems, Incorporated
2570 West El Camino Real
Suite 309
Mountain View, California 94040

9. APPLICANT ORGANIZATION *(Name, address, and congressional district)*
Raya Systems, Incorporated
2570 West El Camino Real
Suite 309
Mountain View, California 94040
12th Congressional District

10. ENTITY IDENTIFICATION NUMBER
77-0207109

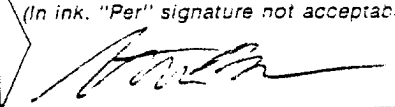
11. SMALL BUSINESS CERTIFICATION
☒Small business
☐Minority and disadvantaged
☐Woman-owned

12. NOTICE OF PROPRIETARY INFORMATION
The information identified by asterisks (*) on pages _____ of this application constitutes trade secrets or information that is commercial or financial and confidential or privileged. It is furnished to the Government in confidence with the understanding that such information shall be used or disclosed only for evaluation of this application; provided that, if a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information herein to the extent provided by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

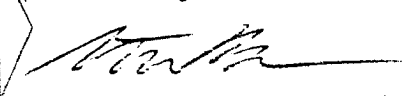
13. DISCLOSURE PERMISSION STATEMENT
If this application does not result in an award, is the Government permitted to disclose the title only of your proposed project, and the name, address and telephone number of the corporate official of your firm, to organizations that may be interested in contacting you for further information or possible investment?
☒YES ☐NO

14. CORPORATE OFFICIAL *(Name, title, address and telephone number)*
Stephen J. Brown
President, Raya Systems, Inc.
2570 W El Camino Real, Ste 309
Mountain View, CA 94040
(415) 949-3933

15. PRINCIPAL INVESTIGATOR ASSURANCE:
I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. Willful provision of false information is a criminal offense *(U.S. Code, Title 18, Section 1001).*

SIGNATURE OF PERSON NAMED IN 3a *(In ink. "Per" signature not acceptable)*

DATE 12/14/90

16. CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true and complete to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as the result of this application. A willfully false certification is a criminal offense *(U.S. Code, Title 18, Section 1001).*

SIGNATURE OF PERSON NAMED IN 14. *(In ink. "Per" signature not acceptable)*

DATE 12/14/90

ABSTRACT OF RESEARCH PLAN

NAME, ADDRESS AND TELEPHONE NUMBER OF APPLICANT ORGANIZATION

Raya Systems, Incorporated
2570 West El Camino Real, Suite 309
Mountain View, California 94040
(415) 949-3933

YEAR FIRM FOUNDED	NO. OF EMPLOYEES (*include all affiliates*)
1988	seven

TITLE OF APPLICATION

Computer Game for Diabetes Education

KEY PROFESSIONAL PERSONNEL ENGAGED ON PROJECT

NAME	POSITION TITLE	ORGANIZATION
Stephen J. Brown	President and Principal Investigator	Raya Systems, Inc.
Dr. Mark Lepper	Professor and Chairman, Department of Psychology	Stanford University
Dr. Raymond Hintz	Professor and Head, Pediatric Endocrinology	Stanford University Medical Center

ABSTRACT OF RESEARCH PLAN: State the application's long-term objectives and specific aims, making reference to the health-relatedness of the project, describe concisely the methodology for achieving these goals, and discuss the potential of the research for technological innovation and commercial application. Avoid summaries of past accomplishments and the use of the first person.

The abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. Since abstracts of funded applications may be published by the Federal Government, do not include proprietary information. DO NOT EXCEED 200 WORDS.

This proposal seeks support for the development and evaluation of an educational computer game for children with diabetes. The goal is to impart essential knowledge and encourage positive attitudes and behaviors. Diabetes is managed largely by patients themselves; patient knowledge and attitude are critical to the success of any treatment. Raya Systems has created a prototype role-playing computer game to address these needs. In the formative phase of this study, experts in education and pediatric endocrinology will evaluate this prototype, and children at a pediatric diabetes ward will play it. The prototype will be modified on the basis of this evaluation. In the summative phase, the impact on in-patient diabetes education will be studied. On alternating months over a four month period, the game will be used at pediatric diabetes education sessions. Children, parents and physicians will be surveyed, and the impact on children's knowledge, attitudes, communication and cooperation with peers will be observed. The final report will assess the game's effectiveness for diabetes education, and will recommend a design for a Nintendo® game. Raya Systems is a licensed Nintendo® developer, and in Phase II, the Nintendo® game will be programmed. The final product will be marketed to pediatricians and parents with diabetic children.

Provide key words (8 maximum) to identify the research or technology.

Computer Game for Diabetes Education

Provide a brief summary of the potential commercial applications of the research.

The research will result in a marketable video game to aid in education of children with diabetes which can be sold to parents, teachers, and physicians.

PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR: Stephen J. Brown

BUDGET FOR PHASE I
DIRECT COSTS ONLY

FROM 7/1/91 THROUGH 12/31/91

PERSONNEL (Applicant organization only) NAME	ROLE IN PROJECT	1 TYPE EMPL.	2 % OF EMPL.	3 EFFORT ON PROJ.	DOLLAR AMOUNT REQUESTED (Omit ce SALARY	FRINGE BENEFITS	TOTAL
Stephen J. Brown	Principal Investigator	1.0	50	0.5	36,000		18,000
Aaron Davis	Programmer	1.0	20	0.2	36,000		7,200
James Wehner	Writer/Artist	1.0	20	0.2	36,000		7,200
SUBTOTALS							

CONSULTANT COSTS	Raymond L. Hintz, M.D., Stanford University Mark R. Lepper, Ph.D., Stanford University	3,000 3,000
EQUIPMENT (Itemize)	IBM PC compatible computer with VGA graphics	3,000
SUPPLIES (Itemize by category)	Computer supplies	200
TRAVEL	DOMESTIC	
	FOREIGN	
PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	
CONTRACTUAL COSTS		
OTHER EXPENSES (Itemize by category)	+ 50%	
TOTAL DIRECT COSTS (Also enter on page 1, item 7a)		$ 41,200

▶ **This figure, when added to the indirect costs, normally may not exceed $50,000.**

OTHER GRANT AND CONTRACT SUPPORT *(see instructions)* ☒ NO ☐ YES

BUDGET JUSTIFICATION

Using continuation pages if necessary, describe the specific functions of the personnel and consultants. Read the instructions and justify all costs requested.

Personnel

Steve Brown will manage the study, direct the focus-group and testing sessions, and draft the final report. Aaron Davis will code revisions to the software between the formative and summative phases. James Wehner will draft and illustrate questionnaires, provide computer art for game revisions, and help produce the final report.

Consultants

Dr. Raymond Hintz will supervise the medical content of the software. Dr. Lepper will provide educational and experimental expertise and guidance.

Equipment

One IBM PC or compatible computer with VGA graphics is requested for testing at the Stanford University Pediatric Endocrinology Ward's classrooms.

Supplies

Computer supplies are needed for the programming and testing components of the research.

RESOURCES AND ENVIRONMENT

1. FACILITIES: Describe the facilities to be used and briefly indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Include laboratory, clinical, animal, computer, and office facilities at the applicant organization, at any other performance site listed on the FACE PAGE, and at sites for field studies. Using continuation pages if necessary, include an explanation of any consortium arrangements with other organizations.

Raya Systems employs 7 persons, and has a third floor office of approximately 3,000 square feet. Secure storage, telephones and a conference room will be available. The Stanford University Pediatric Endocrinology Ward will provide classrooms for use in the study.

2. MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

One IBM PC computer will be made available at the Raya Systems office for coding and revision of the prototype.

3. ADDITIONAL INFORMATION: Provide any other information describing the environment for the project. Identify support services such as consultants, secretarial, machine shop, and electronics shop, and the extent to which they will be available to the project.

Photocopying and other office services are near to Raya Systems' offices.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

NOTICE OF GRANT AWARD

DATE ISSUED: 09/04/91

GRANT NUMBER: HUD-3 (AHR-B)
1 R43 DK44402-01

TYPE OF AWARD: SMALL BUSINESS INNOVATION RESEARCH PROG
AUTHORIZED BY: 42 USC 241 42 CFR PART 52 15 USC 638

TOTAL PROJECT PERIOD:
From 09/05/91 Through 03/05/92

AWARDED BY:
NAT INST OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Title of Project or Area of Training
COMPUTER GAME FOR DIABETES EDUCATION

Grantee Organization
RAYA SYSTEMS INCORPORATED
2570 WEST EL CAMINO REAL
SUITE 309
MOUNTAIN VIEW, CA 94040

Principal Investigator/Program Director/Awardee
BROWN, STEPHEN J
RAYA SYSTEMS INCORPORATED
2570 WEST EL CAMINO REAL
SUITE 309
MOUNTAIN VIEW, CA 94040 12

APPROVED BUDGET
FOR BUDGET PERIOD 09/05/91 Through 03/05/92

Salaries and Wages .....$	32,400
Fringe Benefits	6,000
Total Personnel Costs .....$	3,000
Consultant Costs	200
Equipment	
Supplies	
Travel - Domestic	
- Foreign	
Patient Care - Inpatient	
- Outpatient	
Alterations and Renovations	
Consortium/Contractual Costs	
.....	
.....	
Trainee Stipends	
Trainee Tuition and Fees	
Trainee Travel	
TOTAL DIRECT COSTS →	$ 41,600

When PHS Prior Approval is required for rebudgeting, submit requests to Grants Management Official below.

AWARD COMPUTATION

DIRECT COSTS .....$	41,600
INDIRECT COSTS .....$*	8,000
TOTAL.....$	49,600
Less Unobligated Balance [Prior Period(s)] $	0
AMOUNT OF THIS AWARD → $	49,600

Base Dollars × Rate Percentage = Indirect Costs $*

SUPPORT RECOMMENDED FOR REMAINDER OF PROJECT PERIOD**

Budget Period	Total Direct Costs (Includes Stipends)	Stipends
02	NONE	

**Subject to availability of funds and satisfactory progress.

REMARKS
AMOUNT AWARDED IS THE MAXIMUM ALLOWABLE CEILING TO BE REIMBURSED UNDER THIS GRANT.

#GRANTS MANAGEMENT: MR BRUCE R. BUTRUM (301) 496-7467

SEE ATTACHED FOR TERMS OF ACCEPTANCE AND ANY ADDITIONAL TERMS AND CONDITIONS.

TERMS OF ACCEPTANCE: By acceptance of funds awarded under this grant, the grantee acknowledges that it will comply with terms and conditions in the following: (1) Legislation noted above; (2) Regulations cited above; (3) Special provisions noted above under remarks or attached to this notice; (4) 45 CFR Part 74 or 92, as applicable; (5) PHS Grants Administration Manual; (6) PHS Grants Policy Statement. The above order of precedence shall prevail.

FY—Common Accounting Number	CRS/Entity Identification No.	PHS List No./Object Class Code	Document Number
1-8425512	1770207109A1	/41.4A	(08)R3DK44402A

PROGRAM OFFICIAL
Charles A. Wells
CHARLES A. WELLS, PH.D.
DIRECTOR, DIABETES RES PROG.
DIV OF DIABETES, ENDOCRINOLOGY
AND METABOLIC DISEASES, NIDDK

PHS Grants Management Official
Thomas G. Turley
THOMAS G. TURLEY
GRANTS MANAGEMENT OFFICER
NAT INSTITUTE OF DIABETES AND
DIGESTIVE AND KIDNEY DISEASES

Expiration Date 1/31/92

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

SMALL BUSINESS INNOVATION RESEARCH PROGRAM
PHASE I GRANT APPLICATION

FOLLOW INSTRUCTIONS CAREFULLY

LEAVE BLANK		
TYPE	ACTIVITY	NUMBER
REVIEW GROUP		FORMERLY
COUNCIL/BOARD *(Month/year)*		DATE RECEIVED

1. TITLE OF APPLICATION *(Do not exceed 56 typewriter spaces)*
Microcomputer Attention Battery for School-age Children

2. SBIR SOLICITATION NO **SBIR 91-2**

3. PRINCIPAL INVESTIGATOR ☐ New Investigator

3a. NAME *(Last, first, middle)*
Brown, Stephen James

3b. SOCIAL SECURITY NO.
539-66-5116

3c. POSITION TITLE
President, Raya Systems, Inc.

3d. MAILING ADDRESS *(Street, city, state, zip code)*
2570 West El Camino Real
Suite 309
Mountain View, CA 94040

3e. TELEPHONE *(Area code, number and extension)*
(415) 949-3933

4. HUMAN SUBJECTS
☐NO ☒YES { ☒Exemption # 2, 3 OR ☐Form HHS 596 enclosed

5. VERTEBRATE ANIMALS
☒NO ☐YES

6. DATES OF PROJECT PERIOD
From: 3/1/92 *Through:* 8/31/92

7. COSTS REQUESTED
7a. Direct Costs $ 50,000
7b. Total Costs $ 50,000

8. PERFORMANCE SITES *(Organizations and addresses)*
University of Nebraska-Lincoln
Dept. of Educational Psychology
116 Bancroft Hall
Lincoln, NE 68588

Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040

9. APPLICANT ORGANIZATION *(Name, address, and congressional district)*
Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040
12th Congressional District

10. ENTITY IDENTIFICATION NUMBER
77-0207109

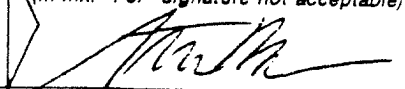
11. SMALL BUSINESS CERTIFICATION
☒Small business
☐ Minority and disadvantaged
☐Woman-owned

12. NOTICE OF PROPRIETARY INFORMATION
The information identified by asterisks (*) on pages _____ of this application constitutes trade secrets or information that is commercial or financial and confidential or privileged. It is furnished to the Government in confidence with the understanding that such information shall be used or disclosed only for evaluation of this application; provided that, if a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information herein to the extent provided by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

13. DISCLOSURE PERMISSION STATEMENT
If this application does not result in an award, is the Government permitted to disclose the title only of your proposed project, and the name, address and telephone number of the corporate official of your firm, to organizations that may be interested in contacting you for further information or possible investment?
☐YES ☐NO

14. CORPORATE OFFICIAL
(Name, title, address and telephone number)
Stephen James Brown, President
Raya Systems, Inc.
2570 West El Camino Real, #309
Mountain View, CA 94040
(415) 949-3933

15. PRINCIPAL INVESTIGATOR ASSURANCE:
I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. Willful provision of false information is a criminal offense *(U.S. Code, Title 18, Section 1001).*

SIGNATURE OF PERSON NAMED IN 3a *(In ink. "Per" signature not acceptable)*

DATE 8/14/91

16. CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true and complete to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as the result of this application. A willfully false certification is a criminal offense *(U.S. Code, Title 18, Section 1001).*

SIGNATURE OF PERSON NAMED IN 14. *(In ink. "Per" signature not acceptable)*

DATE 8/14/91

PHS 6246-1 (Rev. 12/87)

ABSTRACT OF RESEARCH PLAN

NAME, ADDRESS AND TELEPHONE NUMBER OF APPLICANT ORGANIZATION

Raya Systems, Inc.
2570 West El Camino Real, #309
Mountain View, CA 94040
(415) 949-3933

YEAR FIRM FOUNDED	NO. OF EMPLOYEES (*include all affiliates*)
1988	8 (eight)

TITLE OF APPLICATION

Microcomputer Attention Battery for School-age Children

KEY PROFESSIONAL PERSONNEL ENGAGED ON PROJECT

NAME	POSITION TITLE	ORGANIZATION
Stephen Brown, PI	President	Raya Systems, Inc.
Todd Ramming	Project Manager	Raya Systems, Inc.
Gregg Wright, M.D., M.Ed.	Assoc, Prof. of Educ. Psych. & of Pediatrics	University of Nebraska-Lincoln and Omaha
Barbara Plake, Ph.D.	Director, Buros Inst. of Mental Measurements	University of Nebraska-Lincoln
Jerry Halpern, Ph.D.	Senior Research Associate	Stanford University Div. of Biostatistics

ABSTRACT OF RESEARCH PLAN: State the application's long-term objectives and specific aims, making reference to the health-relatedness of the project, describe concisely the methodology for achieving these goals, and discuss the potential of the research for technological innovation and commercial application. Avoid summaries of past accomplishments and the use of the first person.

The abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. Since abstracts of funded applications may be published by the Federal Government, do not include proprietary information. DO NOT EXCEED 200 WORDS.

It is widely accepted that children who fulfill the DSM-III-R criteria for Attention Deficit-Hyperactivity Disorder (ADHD) are a heterogeneous group, but reliable methods do not exist for defining identifiable homogenous subgroups. The proposed research will develop a microcomputer-based battery of tasks which will assess several aspects of auditory and visual attention in children between five and 14 years of age. As a primary objective, the battery should identify those ADHD children whose functioning of neuropsychologic mechanisms of attention is significantly impaired in comparison with a normal population. Secondarily, it is aimed that of those children recognized as neuropsychologically deficient, nearly homogeneous subgroups may be identified in a way that is both statistically and *clinically* significant. These subgroupings will be indicators of which of the several neuropsychologic mechanisms participating in attention are to be suspected as primary deficits. Experts in educational psychology, psychological measurements and biostatistics will participate in the design and final critical assessment of the attention battery, and an informal trial will be carried out on about 20 children in Phase I to assess the feasibiltity of norming and validating the attention battery with controlled populations in Phase II.

Provide key words (6 maximum) to identify the research or technology.

"ADHD," "Attention Deficit," "Hyperactivity," "Computer," "Diagnostic Trial"

Provide a brief summary of the potential commercial applications of the research.

Evidence of the need for a diagnostic test beyond the subjective DSM-III-R criteria which is capable of identifying homogeneous subgroups of ADHD is manifested by the variability of diagnosis and treatment across physicians, teachers, parents and regions. The normed and validated diagnostic test to result from the proposed research would be of evident commercial application, both in pediatric use or in the screening clinic/school setting.

PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR: Stephen Ja...

BUDGET FOR PHASE I
DIRECT COSTS ONLY

FROM 3/1/92 THROUGH 8/31/92

PERSONNEL (Applicant organization only) NAME	ROLE IN PROJECT	1 TYPE EMPL.	2 % OF EMPL.	3 EFFORT ON PROJ.	DOLLAR AMOUNT REQUESTED (Omit cents) SALARY	FRINGE BENEFITS	TOTALS
Stephen Brown	Principal Investigator	1.0	25%	0.25	42,000		$10,500
Todd Ramming	programmer	1.0	40%	0.4	42,000		$16,800
Jim Wehner	writer/artist	1.0	25%	0.25	30,000		$7,500
SUBTOTALS							

CONSULTANT COSTS	Gregg Wright, M.D.,M.Ed., Univ. of Nebraska (50h @ $100/h)	$5,000
	Barbara Plake, Ph.D., Univ. of Nebraska (10h @ $100/h)	$1,000
	Jerry Halpern, Ph.D., Stanford University (10h @ $100/h)	$1,000
EQUIPMENT (Itemize)		
	2 X IBM PC-compatible 386SX computer with SVGA graphics and monitor	$5,500
	2 X beyerdynamic audiometric calibrated headphones (DT 48-A)	$500
	Valentino royalty-free sampled sounds library	$200
	Sony 8-times oversampling CD-player with digital output	$400
	2 X SoundBlaster Pro Stereo Card (PC)	$500
	SoundBlaster development kit (software)	$100
SUPPLIES (Itemize by category)		
	miscellaneous computer supplies	$500
TRAVEL	DOMESTIC	
	FOREIGN	
PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	
CONTRACTUAL COSTS		
OTHER EXPENSES (Itemize by category)		
	freight (shipping of assembled attention battery unit to Nebraska performance site; routine close correspondence between sites in California and Nebraska via Federal Express)	$500
TOTAL DIRECT COSTS (Also enter on page 1, item 7a)		$
▶ This figure, when added to the indirect costs, may not exceed $50,000.		$50,000

OTHER GRANT AND CONTRACT SUPPORT *(see instructions)* ☐ NO ☒ YES

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

NOTICE OF GRANT AWARD

DATE ISSUED: MAR 10 1992

GRANT NUMBER: HUD-1 (AHR-E
1 R43 HD29325-01 HLI

TYPE OF AWARD: SMALL BUSINESS INNOVATION RESEARCH PROG
AUTHORIZED BY: 42 USC 241 42 CFR PART 52 15 USC 638

TOTAL PROJECT PERIOD:
From 03/10/92 Through 09/09/..

AWARDED BY:
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Title of Project or Area of Training
MICROCOMPUTER ATTENTION BATTERY FOR SCHOOL AGE CHILDREN

Grantee Organization
RAYA SYSTEMS INCORPORATED
2570 WEST EL CAMINO REAL
SUITE 309
MOUNTAIN VIEW, CA 94040

Principal Investigator/Program Director/Awardee
BROWN, STEPHEN J BS
RAYA SYSTEMS INCORPORATED
2570 WEST EL CAMINO REAL
SUITE 309
MOUNTAIN VIEW, CA 94040 12

APPROVED BUDGET

FOR BUDGET PERIOD 03/10/92 Through 09/09/92

Salaries and Wages .....$	34,800
Fringe Benefits	
Total Personnel Costs .....$	34,800
Consultant Costs	7,000
Equipment	7,200
Supplies	500
Travel - Domestic	
- Foreign	
Patient Care - Inpatient	
- Outpatient	
Alterations and Renovations	
Consortium/Contractual Costs	
Other	500
.....	
Trainee Stipends	
Trainee Tuition and Fees	
Trainee Travel	
TOTAL DIRECT COSTS →	$ 50,000

When PHS Prior Approval is required for rebudgeting, submit requests to Grants Management Official below.

AWARD COMPUTATION

DIRECT COSTS .....$	50,000
INDIRECT COSTS .....$*	0
TOTAL .....$	50,000
Less Unobligated Balance [Prior Period(s)] $	0
AMOUNT OF THIS AWARD → $	50,000

Base Dollars × Rate Percentage = Indirect Costs $*

SUPPORT RECOMMENDED FOR REMAINDER OF PROJECT PERIOD**

Budget Period	Total Direct Costs (Includes Stipends)	Stipends
02	NONE	

**Subject to availability of funds and satisfactory progress.

REMARKS
AMOUNT AWARDED IS THE MAXIMUM ALLOWABLE CEILING TO BE REIMBURSED UNDER THIS GRANT.

GRANTS MGMT CONTACT: CHARLETTE JEFFERSON (301)496-1303; FAX NO. (301)402-0915

PROGRAM CONTACT: REID LYON, PHD (301) 496-6591; FAX NO (301) 402-2085

SEE ATTACHED FOR TERMS OF ACCEPTANCE AND ANY ADDITIONAL TERMS AND CONDITIONS.

TERMS OF ACCEPTANCE: By acceptance of funds awarded under this grant, the grantee acknowledges that it will comply with terms and conditions in the following: (1) Provisions of the appropriation act(s) cited above; (2) Regulations cited above; (3) Special provisions noted above under remarks or attached to this notice; (4) 45 CFR Part 74 or 92, as applicable; (5) PHS Grants Administration Manual; (6) PHS Grants Policy Statement. The above order of precedence shall prevail.

FY—Common Accounting Number	CRS/Entity Identification No.	PHS List No./Object Class Code	Document Number
2-8421318	17702071094A1	/41.4A	(08)R3HD29325A

PROGRAM OFFICIAL

NORMAN A. KRASNEGOR, PH.D.
CHIEF, HUMAN LEARNING &
BEHAVIOR BR., CTR. FOR RES.
FOR MOTHERS & CHILDREN, NICHD

PHS Grants Management Official

DONALD E. CLARK, CHIEF
OFFICE OF GRANTS AND CONTRACTS
NATIONAL INSTITUTE OF CHILD HLTH
AND HUMAN DEVELOPMENT

PHS 1533 Rev. 7/88 920303 1456

Copies distributed to Principal Investigator, Program Director or Awardee, and Business Office

ATG

Project Plan

KinderCamit

prepared by:
Steve Brown
Jim Wehner

CONFIDENTIAL

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Raya Systems, Inc
2570 West El Camino Real
Suite 309
Mountain View, CA 94040

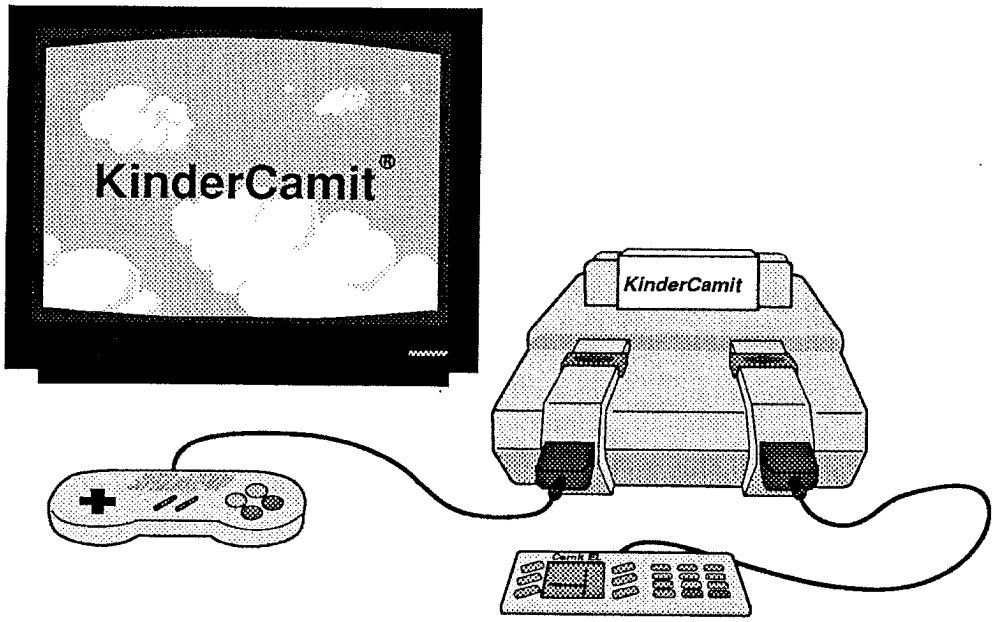
KinderCamit
Preliminary Design Document

Overview

For the person with diabetes, the ability to receive feedback from efforts to maintain blood glucose levels within target ranges is an invaluable aid. Patients today use both paper and electronic logbooks for this purpose. There is much that the combination of an electronic logbook and a computer has to offer, making this feedback easy and up to the minute. However, many potential users are put off by the complexity and cost of a computer and software.

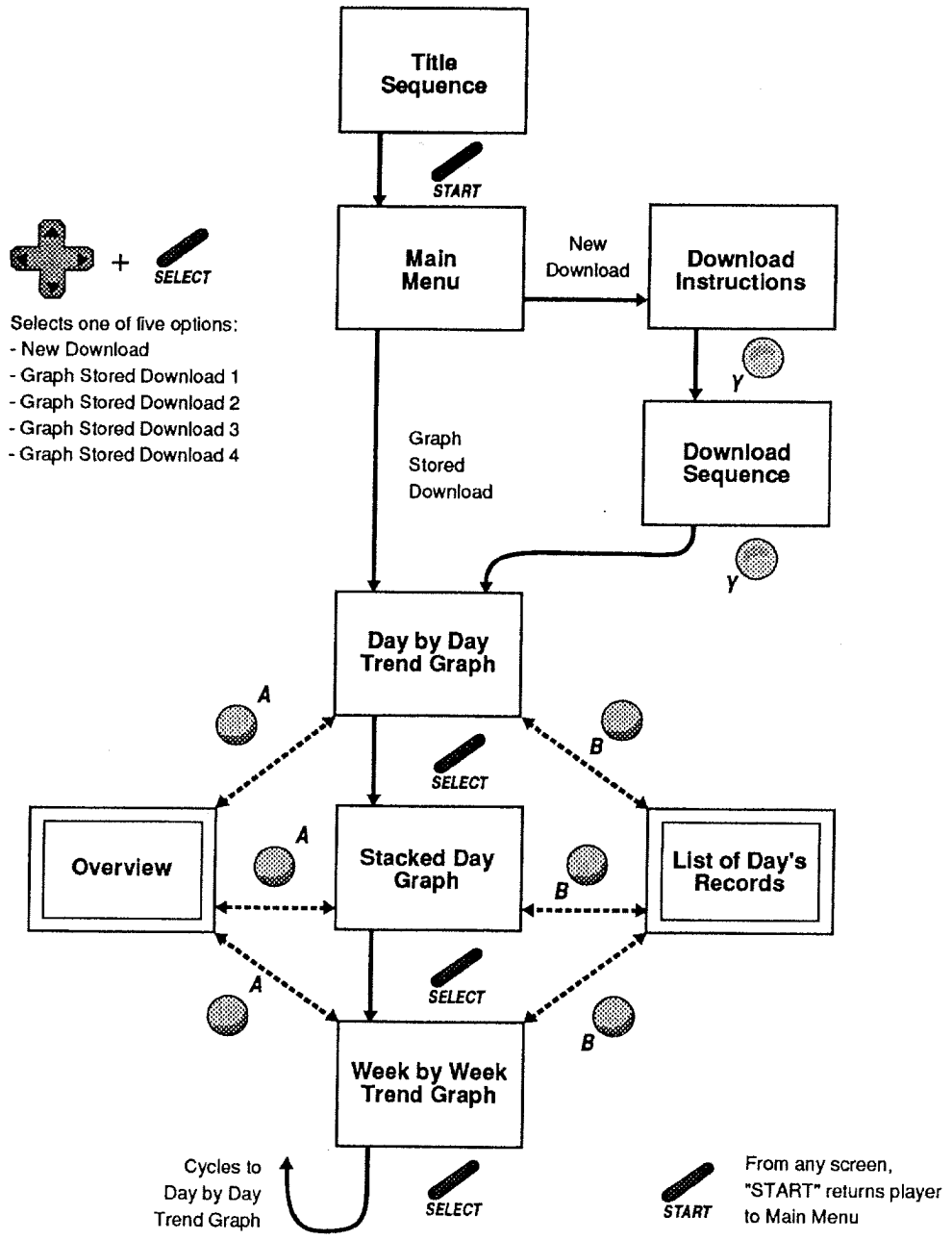
Using the Super Nintendo Entertainment System as a base, KinderCamit can provide such up-to the minute, computer enhanced feedback without the cost or complexity associated with computers. KinderCamit takes information from the Camit EL electronic logbook, stores it, and displays this information in colorful and fun graphs and charts. All of this is done easily, quickly, and inexpensively.

KinderCamit is designed with children in mind, although it would be a useful tool for an adult or even for a physician explaining a treatment plan to a patient.



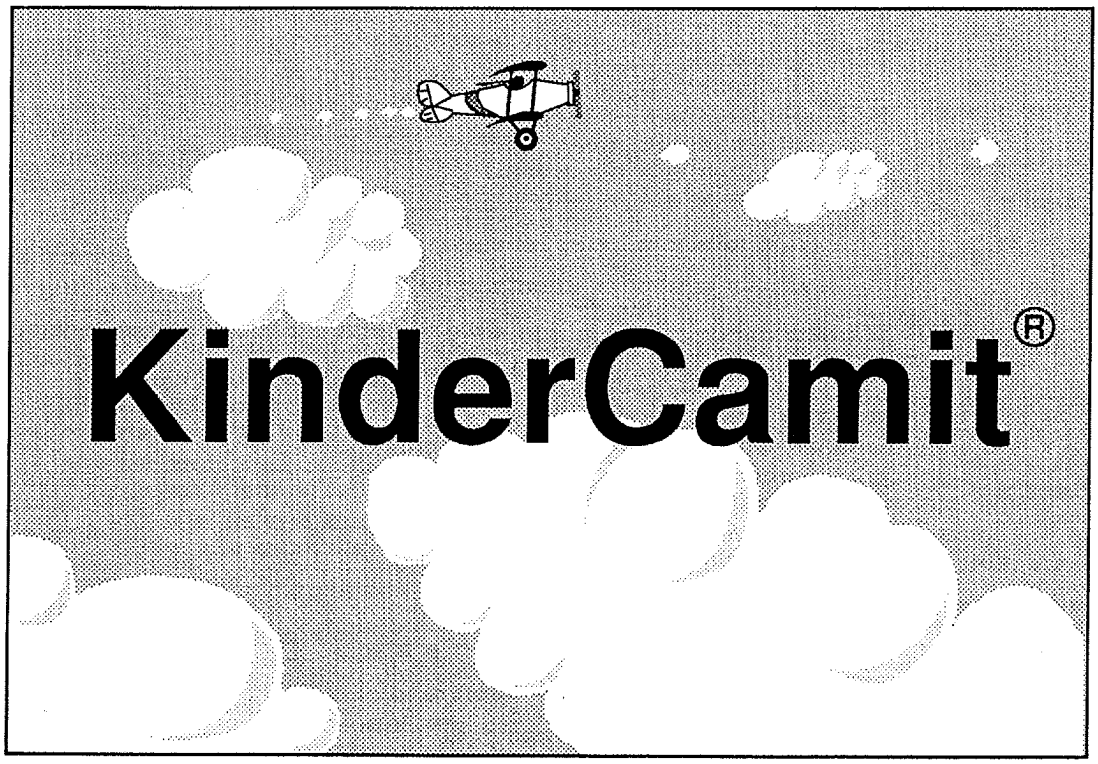
The system consists of the KinderCamit Super Nintendo Game Pak, A Super Nintendo Entertainment System, and a custom cable for attaching the Camit EL to the Super NES.

KinderCamit -overview of screens



The screens in this diagram are explained in detail in the following sections.

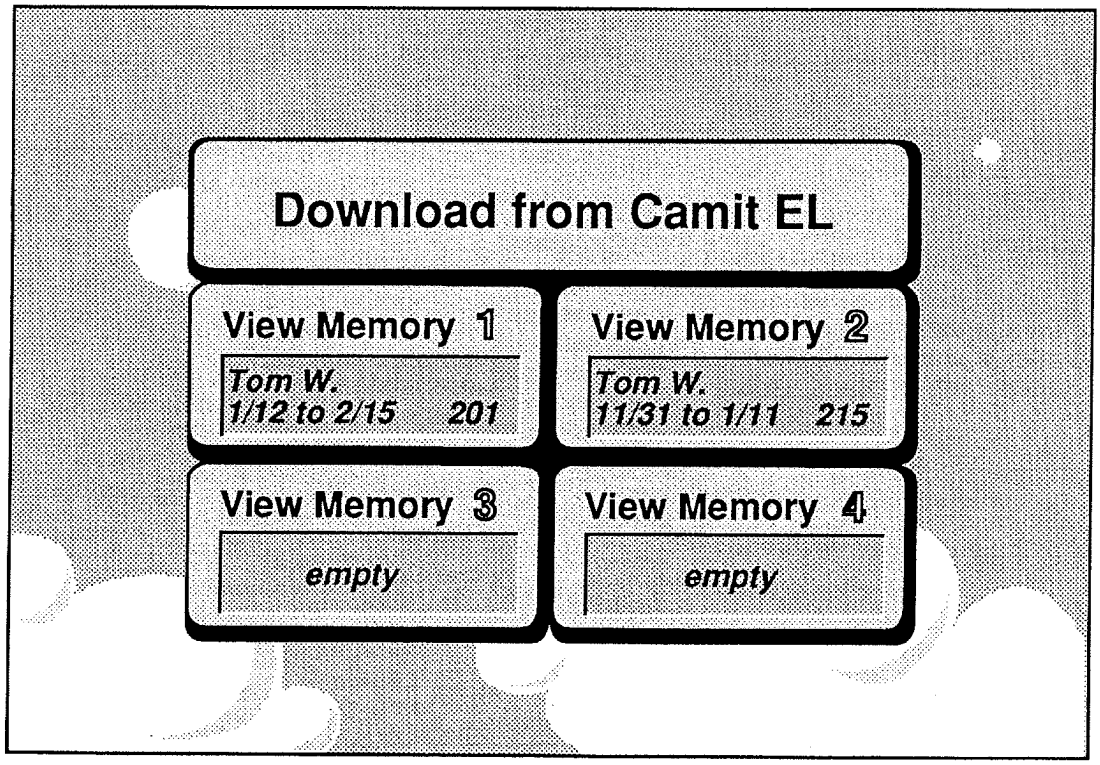
Title Screen



This screen will appear at power on. The jet fighter, biplane, and balloon from the three graphs periodically buzz through the picture. A corporate logo may be included easily.

Options: "start" -> main menu

Main Menu

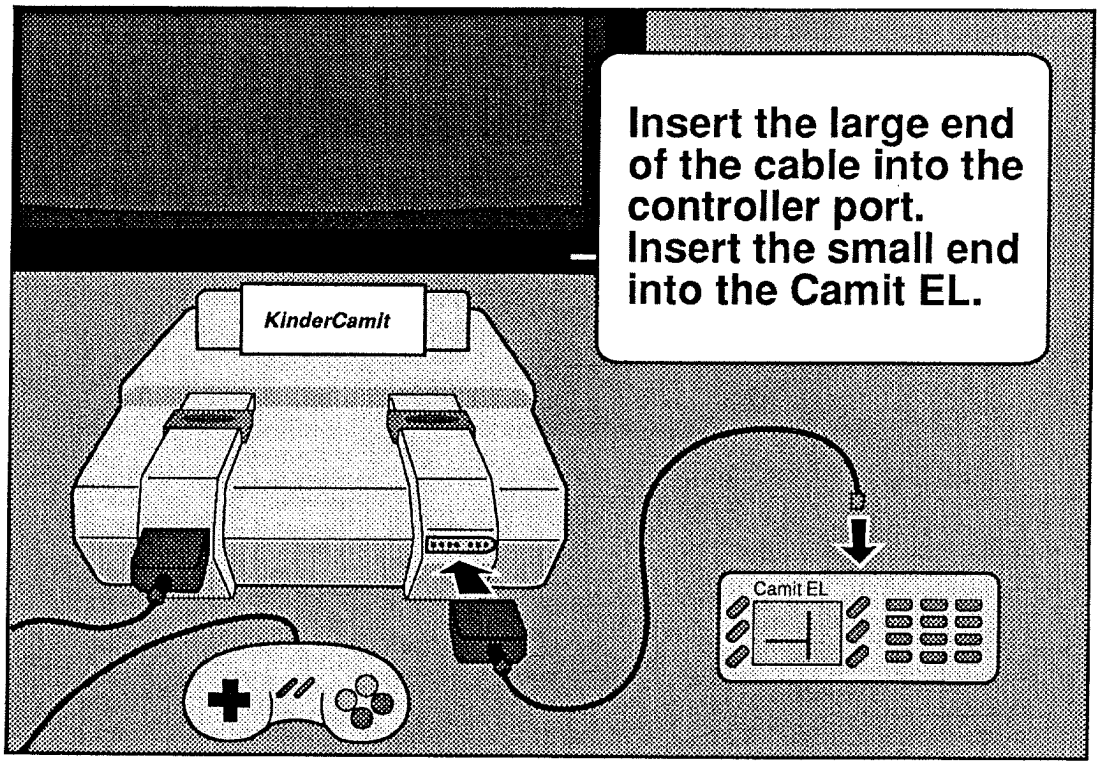


The main menu gives the player access to all the main functions of KinderCamit. A new download is initiated by highlighting the download button. Alternatively, any download in one of the four "memory slots" can be graphed. The player highlights the desired button with the directional controller and presses "select".

This main menu can be reached at any time by pressing the "select" button.

Options: directional controller & "select" to choose

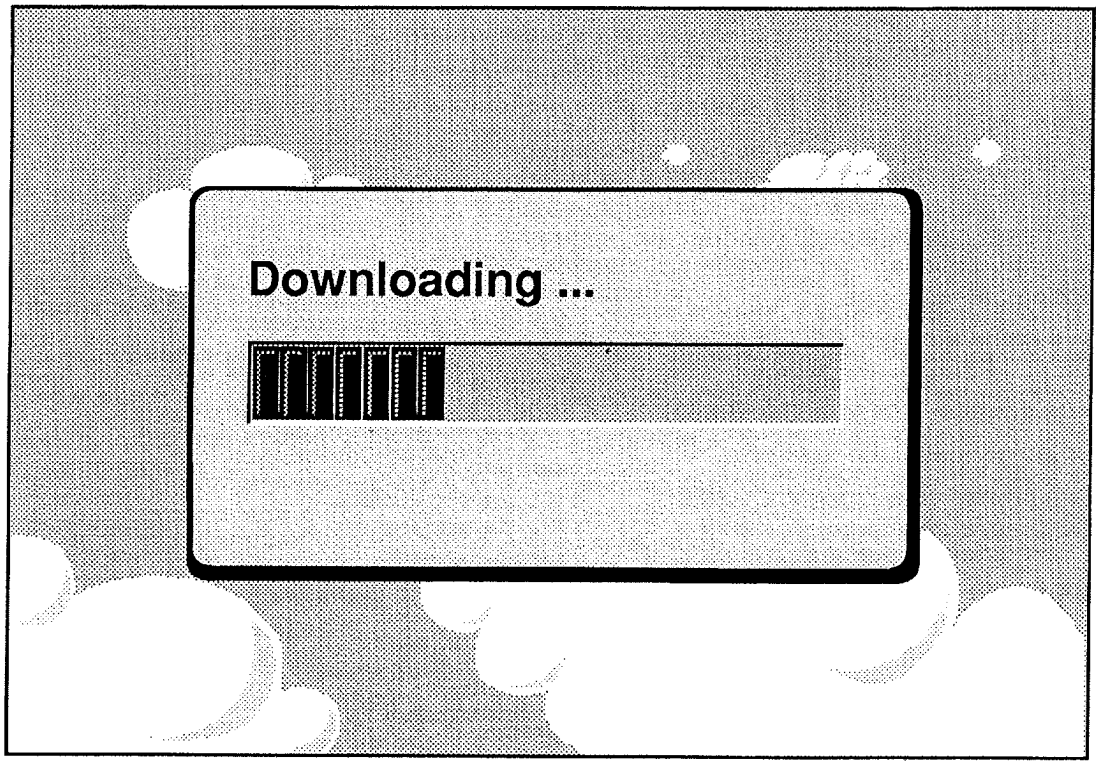
Download Instructions



For ease of use, the simple task of attaching the Camit EL to the Super NES unit is graphically explained with this screen.

Options: "Y" -> download sequence

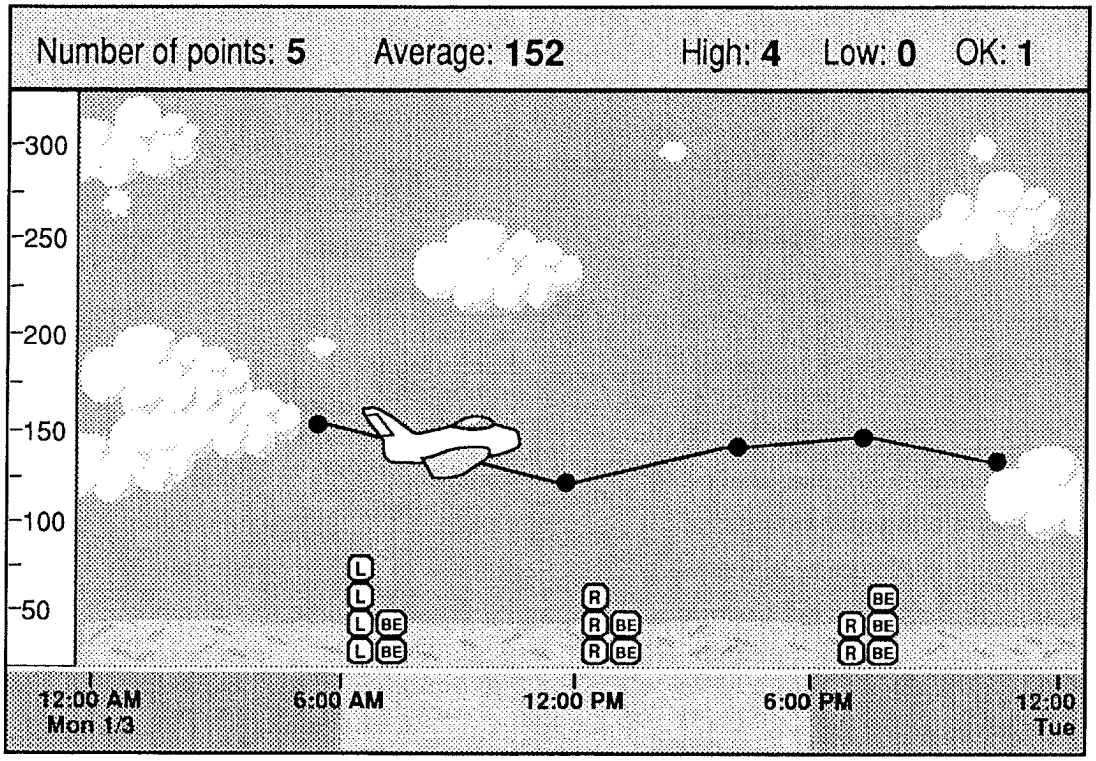
Download Sequence



The progress of the download is displayed with this screen. When the download is complete, the total number of records download is displayed under the status bar.

Options: "Y" -> download sequence

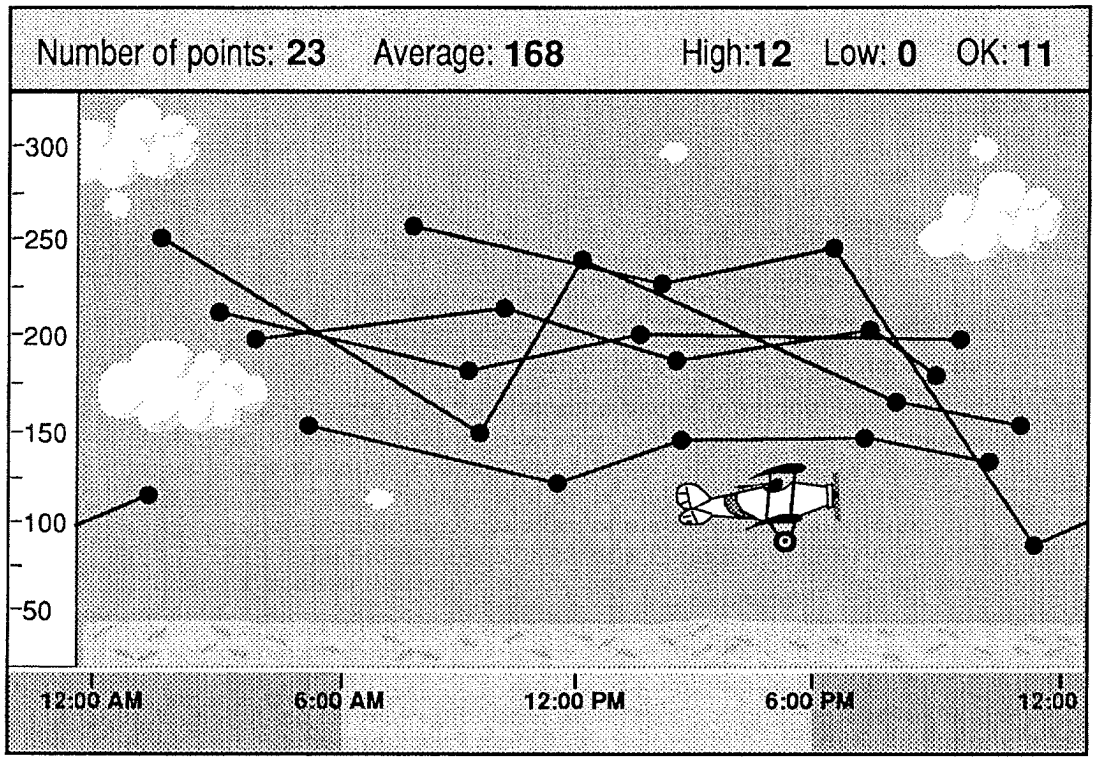
Day by Day Trend Graph



The Day by Day graph presents the records from a download or memory slot in chronological order, one day at a time. The player can move the jet forward and backward along the graph. At hypoglycemic incidents, the plane bumps along the ground; hyperglycemic incidents cause the plane to spin out of control. Food and two types of insulin are marked with incremental histograms. Between-record intervals separated by enough time that a connecting line is not appropriate are obscured by clouds. The plane flies behind these clouds.

Options: "A" -> Overview Screen
"B" -> List of Day's Records
"select" -> Stacked Day Graph.

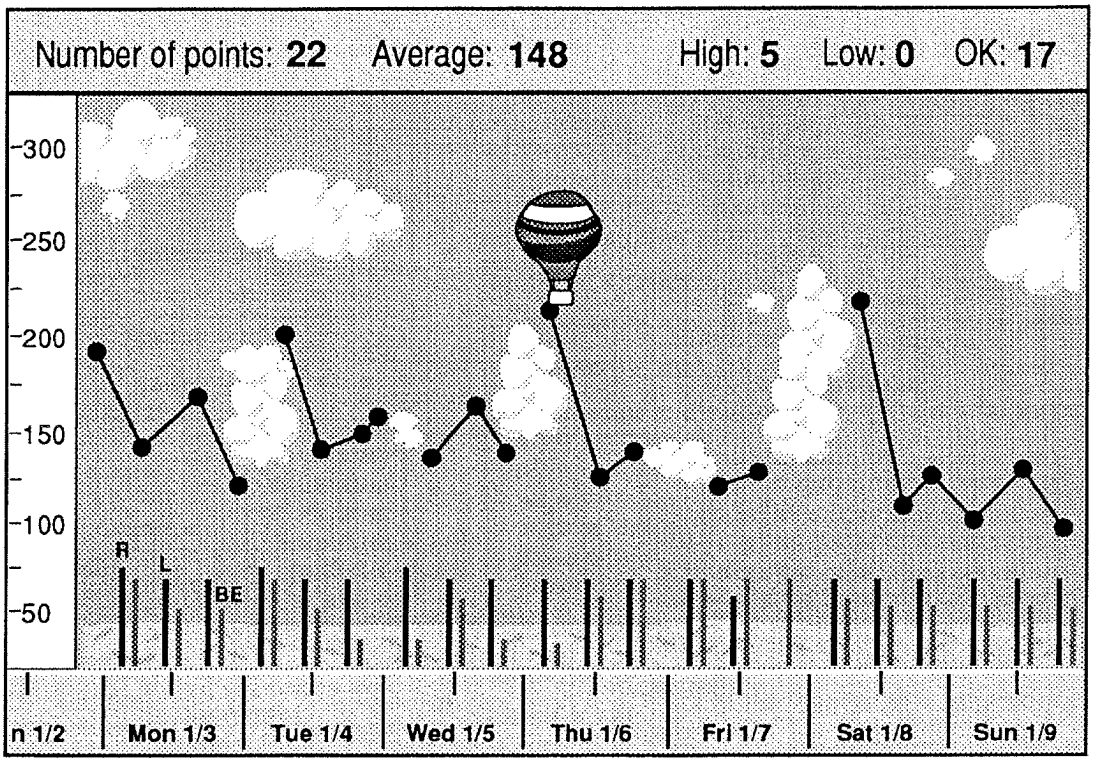
Stacked Day Graph



The Stacked Day graph presents each day's records from a download or memory slot overlayed on the same day's graph. The player can move the biplane up, down, forward and backward along the graph and the average for that time of day is displayed on the top line. The plane flies behind the clouds.

Options: "A" -> Overview Screen
"B" -> List of Day's Records
"select" -> Week by Week Graph.

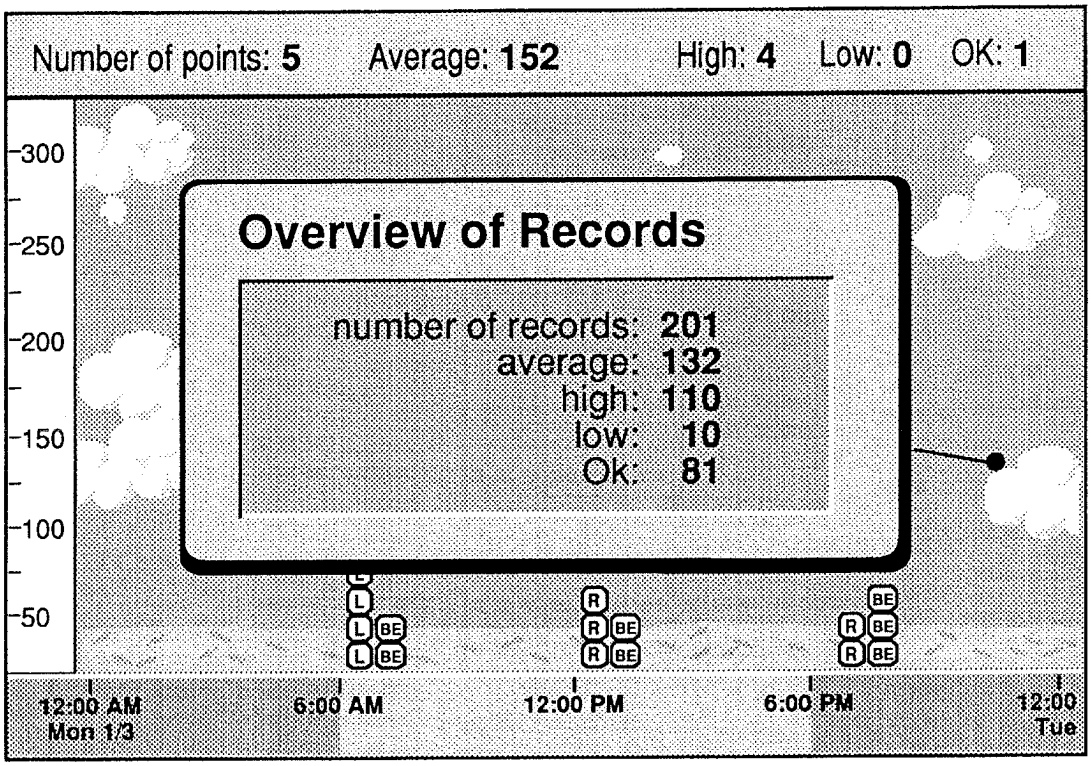
Week by Week Graph



The Week by Week graph presents the records from a download or memory slot in chronological order, one week at a time. The player can move the balloon forward and backward along the graph. At hypoglycemic incidents, the balloon bumps along the ground; hyperglycemic incidents cause the ballon to spin out of control. Food and two types of insulin are marked with colored-line histograms. Between-record intervals separated by enough time that a connecting line is not appropriate are obscured by clouds. The balloon flies behind these clouds.

Options: "A" -> Overview Screen
"B" -> List of Day's Records
"select" -> Day by Day Graph.

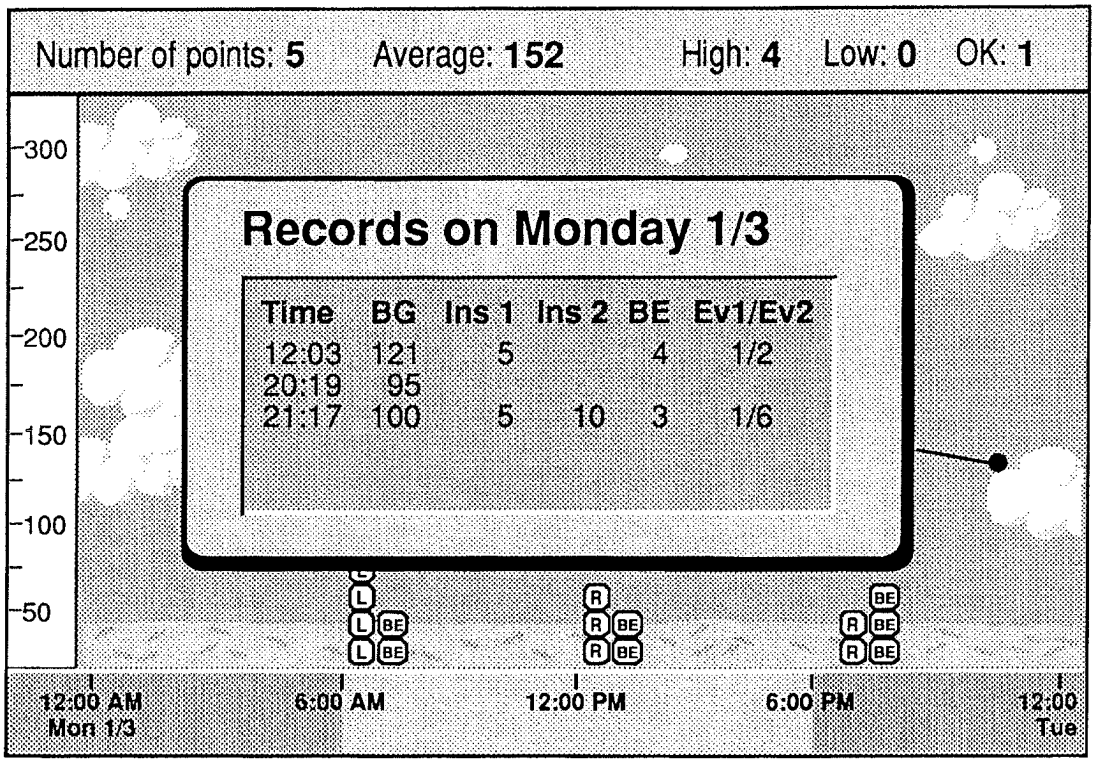
Overview Pop-up Box



This box can be called up from any graph and displays statistics about all the records from the download or memory slot.

Options: **"A" -> removes box**

List of Day's Records



This box can be called up from any graph and displays the records in text form from the day currently active (determined by the position of the plane or balloon).

Options: "A" -> removes box
directional control -> scrolls list, if appropriate

OLES, MORRISON & RINKER
LAWYERS
3300 Columbia Center
701 Fifth Avenue
Seattle, Washington 98104-7007
(206) 623-3427

FACSIMILE COVER SHEET
Telecopier: (206) 682-6234

TO: Steve Brown
FAX: [redacted]
PHONE: [redacted]
CITY: Mountain View, CA.

TO:
FAX:
PHONE:
CITY:

TO:
FAX:
PHONE:
CITY:

* *

CLIENT/MATTER: 6229-001
FROM: Rich Black
DATE: 3/25/92
Page 1 of 4
TIME: 12:32

TO REPORT ANY PROBLEMS WITH TRANSMISSION PLEASE CALL (206) 623-3427 - EXT. 639

DOCUMENT(S) TRANSMITTED: Draft letter

MESSAGE: Steve, I have not proofed or spell-checked this, but I think it addresses N's concerns. Call me before you send it to them.
— Rich

A thermal facsimile is not a permanent copy. A photocopy of this document is advised.

Dear _____:

tel [redacted]
Fax [redacted]
(415)

It was a pleasure meeting with you last Monda[redacted]eciate your support and enthusiasm and I am confident that worki[redacted]hese projects a success for Raya and an attractive new mark[redacted]

As we discussed at our meeting, one primary area of concern bet[redacted]e and my prospective investors is some assurance that Raya System's ideas are not swept up by another Nintendo licensee before we have a chance to convert those ideas into successful products. On the other hand, I appreciate your concern that you don't really know what your various licensees are working on until they present you with a nearly finished game, so you cannot really control what kind of games they may attempt to produce. I have some proposals that I think would adequately meet both of our concerns. First I will explain in more detail why Raya needs the proposal, then I will explain the proposal itself.

Why Raya & its investors need the assurance provided by my proposals.

You indicated that you don't think it is likely that any other licensee will attempt a health/education-related game that is of a quality that Nintendo would approve, basically because Nintendo has rejected most such attempts so far because of their overt commercialism and/or poor quality. However, if our games are successful, all other licensees would then be more interested, and by imitating the financing and production techniques Raya has conceived and developed, may be able to secure Nintendo's interest as well. This puts Raya and its investors in a very precarious position for several reasons.

1) The production of high quality and medically accurate health-related education games requires a great deal of research and testing prior to production. This research and testing inevitably involves a significant amount of public disclosure. For example, it is impossible to test the game on a statistically significant number of children and expect them to keep it a secret. Over the several weeks or months of research, we are confident that the information about our proposed game would leak to a competitor. Equipped with our idea, the competitor could then quickly produce a competing game without investing the time or money on the medical and educational research because it could free-ride on the research that Raya had done. The competitor could then come to you with a proposal for a less expensive game of comparable quality, and Raya would have a difficult time surviving the competition. In short, Raya needs to be assured that it can conduct all the research necessary for a medically and educationally accurate game without the fear of any competitors free-riding on the idea or the research.

2) In addition to the risk of free-riding on particular games or specific health-education issues, I am also concerned about the general concept that Raya is built on: health-education games financed by a corporate sponsor. Now that I have explained it and put all the pieces of the puzzle together, the concept seems simple. So simple in fact, that I am sure other competitors will attempt to imitate it before I have a chance to stabilize my position in the market. Others have come to you with games that were unacceptably commercialized or otherwise flops. But to may knowledge I am the first one to present you with a workable plan for securing a position for Nintendo in the health-education area. Before I go public with that plan, my investors and I need some assurance that none of our competitors will be able to free-ride on my idea and drive me out of the market before I have a chance to recover our initial investment.

3) Raya's investors (primarily the corporate sponsor's such as Novo Nordisk), are considering investing hundreds of thousands of dollars to place a Super Nintendo unit in every pediatrician office in the country. They are willing to do this because they hope to secure a return in public relations because of the target market becoming familiar with its name and associating that name positively with education. However, if, after spending all that money, one of their competitors produces a game to be played on the same Super Nintendo sets, that competitor would be able to free-ride on the first sponsor's investment. This would be unfair and the risk of that happening may discourage Raya's investor's (such as sponsors) from making the initial investment. In short, the investors need some assurance that they can earn an adequate return on this initial capital investment.[1]

4) The health-education related game market is very promising, but relative to the game market in general, is quite narrow. Most Nintendo licensees can survive severe competition in the general game market because there are some _____ million kids that will play any type of game. Raya's proposed games however, are intended to serve a much more specialized market. The asthma game, for example, even assuming an optimistic market penetration of _____%, would only sell _____ copies. This number is so small that I am quite concerned that it would not support more than one producer. This is even more true with respect to the Diabetes game. At least for the foreseeable future, I plan to focus on health-education related games, and am making a conscious decision to restrict my production to this narrow market. In return, my investors and I need some assurance that my fledgling firm can afford to invest in this specialized market without competition from bigger and more established licensees that can afford to risk a loss in this narrow market because they can offset the loss with gains in the general game market.

A proposal providing Raya and its investors the assurance they need to go forward with the games

1) My basic proposal is to have Nintendo grant me a conditional exclusive license to produce games in the health-education area for 2 years. The conditions would be these:

a) That it can be made non-exclusive if Raya ever fails to produce games of the quality and in the quantity that Nintendo requires. This protects you from two risks: 1) my products become inferior and you would want the opportunity to have a different licensee produce health-education games. I certainly don't expect this to happen, but you are entitled to protect yourself from that risk. 2) Raya cannot produce sufficient quantity to meet the demand. This protects you from the possibility that a truly successful product is not optimally marketed because of Raya's size, and would give you the option of allowing a different licensee to fill the gap with a competing product.

b) That it be subject to all the conditions of my current license agreement. For example, it would be restricted to North America.

---

[1] One possible way of addressing this would be for the investors to demand a promise from the pediatricians that they only play the investors' games on their units, and not play any games of competitors. This is inferior to my proposal because 1) it would be very difficult to monitor and police, 2) it would be very difficult to get the pediatricians to make such a promise, 3) it would be a wasteful duplication of resources to create incentives to have a different Super Nintendo set for each different game in each pediatrican's office; it makes much more sense to have one or a few units which can be used to play any health-related educational game in the office.

c) That it would become non-exclusive after 2 years. I and my investors would actually prefer 3 years but we may be able to establish a solid market position within 2 years, and I may be able to persuade my investors to accept only 2 years.

d) That it would only be for the health-education related field. Even broadly-defined (we could work out the wording together), this field is very narrow relative to the entire market available to other Nintendo licensees, so it would work little, if any, hardship on them.

e) That every other Nintendo licensee be notified of Raya's exclusive conditional license as soon as it is granted. This will prevent them from investing time or money in games in the health-education related field only to find out later that it was restricted and that you would not permit it because of your license agreement with me. This not only saves them money, but is fair. It also will remove the temptation for the licensees to try to persuade you to dishonor your agreement with me. I don't expect that you would do that, but I think it would be better if you were not even bothered by such solicitations. The notice could say something like:

"Dear Nintendo Licensee, please take notice that we will not be approving any games produced by you in the health-education field for the next 2 years by reason of an exclusive conditional license agreement we have entered into with another licensee. If you have any question about whether a contemplated game will be considered by us as falling within the health-education field, we recommend that you contact us at the earliest possible date so as to avoid wasted effort by you. If the exclusive conditional license agreement is broken or otherwise becomes non-exclusive, we will notify you immediately."

f) A final optional condition is that it could contain a first right of refusal for Raya. That is, instead of a blanket prohibition on any health-education related games, our license could grant us a first right of refusal to produce any games in the health-education field that are proposed to you. So the first two sentences of the notice would instead read something like this:

"Dear Nintendo Licensee, please take notice that ideas for any games to be produced by you in the health-education field for the next 2 years are subject to a first right of refusal by reason of an exclusive conditional license agreement we have entered into with another licensee. We will only approve games on topics in the health related field produced by you if our exclusive licensee refuses to agree within 60 days to produce a game on that topic. . .

Summary

The proposal accommodates, I think, both our concerns. By virtue of all the conditions on the proposed exclusivity of the license, I also think it is quite reasonable. As I indicated both in this letter and when we met, this matter is of the utmost importance to me, and I hope you will find the proposal acceptable. Of course, if you have any modifications or alternate proposals that would address my (& my investors') needs, I would be happy to discuss them with you.

I look forward to hearing from you.

Sincerely,

_____

Stephen Brown

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

May 13, 1992
Invoice 58596 Page 1

RAYA SYSTEMS
2570 W EL CAMINO REAL
SUITE 309
MT VIEW CA 94040

Our File #C6228-001 For Services Through 04/22/92
Miscellaneous

03/23/92 Review contracts & business strategy with S.Brown.
DSO 1.60 hrs.

03/23/92 Office conference with S.Brown regarding contracts & business strategy.
RB 1.80 hrs.

03/24/92 Telephone call to S.Brown regarding follow up of meeting;Preparation of Letter to Nintendo.
RB .60 hrs.

03/25/92 Draft Letter to Nintendo regarding excl. license;Revise CS Agreement.
RB 4.00 hrs.

03/26/92 Review corporate sponsor contract & Revise.
DSO .30 hrs.

03/26/92 CS Agreement;Revise contracts.
RB 1.40 hrs.

#225

03/27/92 Schedule contract review.
RB .10 hrs.

03/30/92 Review billing Memorandum.
RB .20 hrs.

04/02/92 Office conference with KMM regarding general corporate paperwork.
RB .10 hrs.

04/07/92 Review file;Develop annual corp. legal administrative plan.
RB .40 hrs.

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

04/08/92 Review Correspondence file & contracts.
RB .40 hrs.

04/09/92 Review Correspondence file & old contracts;Legal Research regarding smoke;Call to client.
RB 2.10 hrs.

04/10/92 Legal Research regarding T.Mark & Copyright;Telephone call to Louise regarding status.
RB .80 hrs.

04/18/92 Legal Research regarding trademark,copyright & smoke.
RB 1.50 hrs.

04/20/92 Legal Research regarding trademark,copyright & smoke;Status conference with Steve regarding research,etc.
RB .50 hrs.

04/21/92 Telephone call from Steve;Memorandum to file;Review BM contract.
RB 1.60 hrs.

04/22/92 Review BM contract;Telephone call to S.Brown regarding promo clauses.
RB .70 hrs.

Fees for legal services.....$ 1800.00

ADVANCED COSTS

04/07/92	Federal Express: Delivery to Mr. S. Brown, 3/26/92. RTB	$	10.50
	Postage/Telecopy	$	12.61
	Telephone Charges	$	2.82
	Photocopies	$	6.40
	Word Processing	$	35.00

Total Costs.....$ 67.33

Total fees and costs.....$ 1867.33

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

May 13, 1992

RAYA SYSTEMS Invoice # 58596 Page 3

PLEASE REMIT TOTAL BALANCE DUE.....$ 1867.33

This invoice may not include expense items for which we have not yet been billed.

RAYA SYSTEMS, INC.
2570 W. EL CAMINO REAL #309
MOUNTAIN VIEW, CA 94040

BANK OF AMERICA NT & SA
SAN ANTONIO BRANCH 0448
P.O. BOX 340
MOUNTAIN VIEW, CA 94042
11-35/1210

2219

2 Jun 92

Pay to the Order of Oles, Morrison & Rinker

$ ****1,867.33

housand Eight Hundred Sixty-Seven and 33/100********** Dollars

Oles, Morrison & Rinker
Lawyers
Accounting Dept. 3011
P.O. Box 34936
Seattle, Washington 98124-1936

⑈002219⑈ ⑆121000358⑆ 04482⑈15097⑈ ⑈0001867 33⑈

FAX 05/11/92

to: Hartmut Kassulke
Boehringer Mannheim GmbH
phone: (621) 759-3997
fax : (621) 759-4179

pages: 2 (including this one)

from: Todd Ramming
Raya Systems, Inc.
phone: (415) 949-3933
fax : (415) 949-3935

re: Camit S 2.5

Dear Hartmut,

Thank you for your fax today, and I enjoyed speaking with you. Below I present specifics on our timetable for development of Camit S 2.5.

	B	C	D	E
#1 May 11-15	technical upgrades			
#2 May 18-22	database/conversion			
#3 May 25-29	"			
#4 Jun 1-5	downloading			
#5 Jun 8-12	import			
#6 Jun 15-19	interface/algorithms			
#7 Jun 22-26	"			
#8 Jun 29-3	"			
#9 Jul 6-10	"[a]			
#10 Jul 20-24	multi-user	revised costs to BM[1]		
#11 Jul 27-31	debugging	acceptance by BM		
#12 Aug 3-7	multi-user	user guide		
#13 Aug 10-14	installation	"		formal testing[b]
#14 Aug 17-21	debugging[c]	"[d]	revised costs to BM[2]	
#15 Aug 24-28		"	acceptance by BM	formal testing
#16 Aug 31-4		"[e]	Netware lite app.	"
#17 Sep 7-11			"	"
#18 Sep 14-18			"[f]	"[g]

1 costs revised to provide a new integrated edition of the user guide with enhancements and changes highlighted

2 costs revised to provide discussion of use of Camit S in a networked environment with specific reference to NetWare lite

[a] first application enhanced sent to BM
[b] test plan sent to BM
[c] second application enhanced sent to BM
[d] draft user guide sent to BM
[e] proof user guide sent to BM
[f] proof NetWare lite example sent to BM
[g] final report sent to BM, with final deliverables

Please let me know your comments. I will provide you, in addition to the indicated deliverables, bi-weekly status reports of our progress by fax, and look forward to speaking with you during the completion of this work.

Also, I have a question still remaining from our discussion by phone. In regard to the "marking" byte, is this not still where C (=changed) and M (=manual) are indicated -- information present in the EL as well ?

Best regards,

Todd Ramming

Facsimile Cover Sheet

To: Amy Phillips
Company: 52nd Annual Scientific Sessions - Manager
Phone: 703-549-1500 #349
Fax: 703-836-7439

From: Stephen J. Brown
Company: Raya Systems, Inc.
Phone: 415-949-3933
Fax: 415-949-3935

Date: 05/12/92
Pages including this cover page: 2

Comments:

Faxed 5/12 3:45 pm

American Diabetes Association.

52ND ANNUAL SCIENTIFIC SESSIONS

SPEAKER RELEASE FORM

All symposia of the 52nd Annual Scientific Sessions will be audio-taped for the purpose of selling the audiotapes, contingent upon approval of the speakers.

Please complete and return this form to ADA to authorize audio-taping and sale of the tape of your presentation.

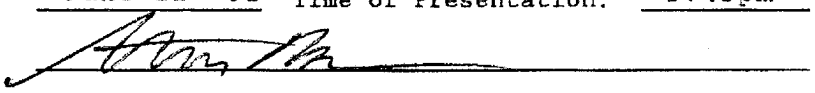
__X__ Yes, you may audio-tape my presentation and sell the audiotape. I understand I will receive no royalties for this use.

_____ No, you may not audio-tape my presentation.

Presenter's Name (Print): Stephen J. Brown

Title of Presentation: New Technology for Diabetes Education: Home Video Games

Date of Presentation: June 22 '92 Time of Presentation: 1:45pm

Presenter's Signature: 

Please complete and return this form by May 15, 1992 to:

Amy Phillips
52nd Annual Scientific Sessions Meeting Manager
American Diabetes Association
National Center
1660 Duke Street
Alexandria, VA 22314
USA
Telephone: 703/549-1500, ext. 349
Fax: 703/836-7439
Telex: 901132

American Diabetes Association.

National Center 1660 Duke Street Alexandria, Virginia 22314 (703) 549-1500 Telex: 901132 Fax: (703) 836-7439

May 4, 1992

Steve Brown
President
Raya Systems
688 Josina
Palo Alto, CA 94306

Dear Mr. Brown:

We are very pleased that you have accepted the invitation to participate in the American Diabetes Association's 52nd Scientific Sessions to be held June 20-23, 1992 in San Antonio, Texas. Your symposium is scheduled to be held Monday, June 22 from 1:45 p.m. - 3:45 p.m. at the San Antonio Convention Center. An Advanced Program is enclosed for your information, and includes registration and housing forms.

As a speaker, your registration fee will be waived; however, you must register for the meeting by completing the enclosed form. ADA will not reimburse travel or expenses. In addition, ADA now requires all speakers to complete a disclosure statement that addresses your relationship(s) with other organizations/industries which you will find enclosed.

All sessions will be taped. Please complete the enclosed speaker release form and audio visual request form and return to the Meetings Department as soon as possible. Also note that sessions will be held in large halls in the San Antonio Convention Center. Please make every effort to ensure that your slides will be clearly visible to all attendees. A guide for making good quality slides is enclosed.

In order to include the correct information concerning your participation in the promotional materials for the '92 meeting, please complete the enclosed form and return it to me as soon as possible.

If you have any questions concerning the program or the meeting, please contact me at 703/549-1500, x281.

We look forward to your participation in the program.

Sincerely,

Linda Cann
Manager, Professional Programs

Enclosures

Officers

Todd E. Leigh, *Chairman of the Board*
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Patricia Stenger, R.N., C.D.E., *Vice President*
Marilyn Moore, *Secretary*
Stephen J. Sanalino, *Treasurer*

Office of the Executive

John H. Graham, IV, *Chief Executive Officer*
Richard Kahn, Ph.D., *Chief Scientific and Medical Officer*
Caroline Stevens, *Chief Operating Officer*

Member of: International Diabetes Federation • Independent Sector • National Health Council • Combined Health Appeal

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

392

EXHIBIT I
PAGE 1 OF 4

June 10, 1992
Invoice 58970 Page 1

RAYA SYSTEMS
2570 W EL CAMINO REAL
SUITE 309
MT VIEW CA 94040

Our File #C6228-001 For Services Through 05/22/92
Miscellaneous

04/23/92	Revise CS Agreement;Preparation of Memorandum to Steve regarding status of contracts & obligations thereunder	
	RB	2.40 hrs.
04/24/92	Review Letter to Steve regarding contracts;Review Steve's Letter re Todd's share;Drafting of reply.	
	RB	1.10 hrs.
04/30/92	Review billing memo.	
	RB	.20 hrs.
05/05/92	Telephone call from Steve regarding contracts,board of directors & general business matters.	
	RB	.40 hrs.
05/05/92	New contract with Sculpured;Review new publisher contract.	
	RB	.40 hrs.
05/06/92	Review new development contract;Telephone call from Steve regarding contracts.	
	RB	.70 hrs.
05/08/92	Review new developer contract.	
	RB	2.40 hrs.
05/11/92	Telephone call to Steve regarding comments regarding contract.	
	RB	.40 hrs.
05/12/92	Review new developer contract provisions.	
	DSO	.20 hrs.

PAYMENTS RECEIVED ON OR AFTER STATEMENT DATE WILL NOT BE REFLECTED ON THIS INVOICE
NET 30-THEREAFTER INTEREST CHARGES AT 12% PER ANNUM ON THE UNPAID BALANCE

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

June 10, 1992
RAYA SYSTEMS Invoice 58970 Page 2

05/12/92 Further Review Letter to Steve regarding risks under New Sculptured contract;Review artist contract.
RB 4.50 hrs.

05/13/92 Letter to S.Brown regarding Sculptured contract;Telephone conf. with S.Brown regarding Letter.
RB 1.50 hrs.

05/14/92 Telephone call to Louise regarding contract.
RB .10 hrs.

05/15/92 Review Correspondence with Structured in preparation for negotiations.
DSO .10 hrs.

05/15/92 Telephone call to S.Brown regarding Letter to Sculptured.
RB 2.10 hrs.

05/18/92 Call to Raya regarding Receipt of fax.
RB .10 hrs.

05/19/92 Review Corp. maint. documents & contracts;Office conference with DSO;Preparation of Letter to S.Brown.
RB 2.90 hrs.

05/20/92 Drafting of Letter to S.Brown;Notice of confid. empl. Agreement / employment Agreement.
RB 3.90 hrs.

05/20/92 Telephone call from S.Brown regarding Sculptured's response to objections;Telephone call to G.Metos.
RB 3.00 hrs.

05/21/92 Revise Sculptured's prop. contract;Drafting of Corp. maintenance Letter;Telephone call from Steve regarding contract.
RB 4.50 hrs.

Fees for legal services.....$ 2808.00

ADVANCED COSTS

05/11/92 Federal Express: Delivery to S. Brown, 4/23/92. RTB $ 8.00

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

June 10, 1992
RAYA SYSTEMS Invoice # 58970 Page 3

Postage/Telecopy	$	67.23
Telephone Charges	$	45.95
Photocopies	$	9.20
Word Processing	$	233.00
Total Costs.....	$	363.38
Total fees and costs.....	$	3171.38
PLEASE REMIT TOTAL BALANCE DUE.....	$	3171.38

This invoice may not include expense items for which we have not yet been billed

RAYA SYSTEMS, INC.
2570 W. EL CAMINO REAL #309
MOUNTAIN VIEW, CA 94040

BANK OF AMERICA NT & SA
SAN ANTONIO BRANCH 0448
P.O. BOX 340
MOUNTAIN VIEW, CA 94042
11-35/1210

2297

30 Jun 92

Pay to the Order of Oles, Morrison & Rinker $ ****3,171.38

Three Thousand One Hundred Seventy-One and 38/100********** Dollars

Oles, Morrison & Rinker
Lawyers
Accounting Dept. 3011
P.O. Box 34936
Seattle, Washington 98124-1936

re Invoice #58970

⑈002297⑈ ⑆121000358⑆ 04482⑈15097⑈ ⑈000317138⑈

Fax Transmission

Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, California 94040

Telephone (415) 949-3933
Fax (415) 949-3935

Sender Steve Brown

Subject

Date 5/31/92

Pages 2

Please deliver to

Name Hartmut Kaßulke

Department SP - MP

Company Boehringer Mannheim

Fax number 011 49 621 759 4179

June 1, 1992

Hartmut Kassulke
Boehringer Mannheim GmbH
Abt. SP-MP
Mannheim, Germany

Dear Hartmut,

I would like to let you know of some new developments at Raya Systems since we last spoke.

In order to allow Todd to immediately concentrate on Camit S 2.5, I hired a senior programmer to take over the project management of Diabcare. Todd is still involved in the project because he knows the source code, but the transfer of day-to-day responsibilities is nearly complete and the project manager should start reporting directly to you in a few weeks. His name is Jim Blum, and he has 16 years of experience in software project management and applications programming.

Beginning July 1, I am hiring an administrative assistant and technical writer who speaks both English and German. I hope to improve our communications by having someone always available to write status reports and translate them to German. We also need to start on the Camit 2.5 and Diabcare documentation. I assure you that everyone on the Boehringer Mannheim projects is working hard to get the job done. Many times we have felt so pressed for time that we have not kept you adequately informed. I recognize that for our work together to continue, we must improve the communications. The increased staff on BM projects should make a significant difference.

The American Diabetes Association has invited me to give a 25 minute presentation in one of the scientific sessions of the ADA conference in San Antonio. I am speaking in place of David Rodbard on Monday, June 22. The title of my presentation is "New Technology for Diabetes Education." We are showing a new product there and holding a press conference as well. Will you be able to come? 25 minutes is a long time for a presentation, and I could have time to discuss Camit.

Sincerely,

Steve Brown

rayasystems

Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040
phone: (415) 949-3933
fax: (415) 949-3935

Meeting June 1, 1992

Introductions

- Steve Brown
- Todd Ramming
- Jim Blum
- Emanuel Bouyssounouse
- Gerard Lum
- Natalie Khatset
- Louise Novak
- Jim Wehner
- Patty Scheurkogel

Raya Systems status

- Boehringer Mannheim
- Novo Nordisk
- NIH
- Nintendo

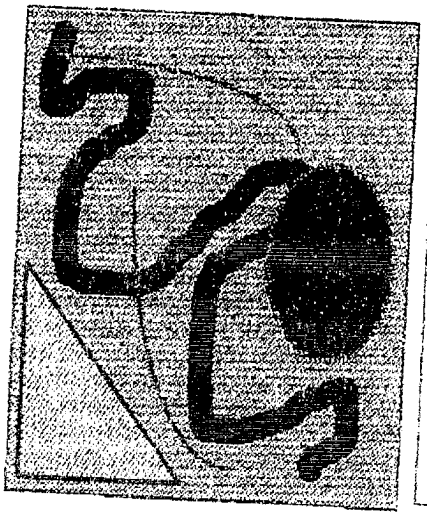
Organization

- Current: BM & NN
- Future: Research, Development, Sales, Finance, Project Management
- New position: sales director?
- New position: Nintendo producer
- New position: administrative support / technical writer

Administrative issues

- Phones
- Supplies
- Support person
- Benefits

06/02/1992 11:59 FROM TO 14159493935 P.01



FAX TRANSMITTAL

Jay Clark
12434 82nd Ave. NE
Kirkland, WA 98034
TEL (206) 820-1057
FAX (206) 820-1245

DATE 6/2/92 FAX (415) 949-3935

TO Raya Systems, Inc.
Attn: Steve Brown

MESSAGE Steve, here is a revised version of the work agreement. I changed wording in the Definitions and Ownership sections in order to clarify that Raya owns the .EXE and all game-specific source code while I retain ownership of the libraries. If you don't call back, I'll assume the agreement is acceptable, sign it, and give it to Louise.

Pages to follow: 2

Jay

Work-Made-for-Hire Agreement

I. Introduction

This is a work made for hire agreement in which Jay Clark (Developer) agrees to provide software development services as an independent contractor to Raya Systems, Inc. (Raya). As consideration for all the duties of Developer herein, Raya shall pay Developer according to the payment schedule set forth in the document attached to this contract, which is incorporated by reference herein.

II. Definitions

A. "Program" shall mean the computer program described in the document attached to this contract, which is hereby incorporated by reference. Program also includes all source code files necessary to compile the computer program. Source code files are text files containing C, C++, or assembler programming language constructs.

B. "Software Development Tools" shall mean all compilers, interpreters, linkers, routines, subroutines, and other programs that are used by Developer to develop the program specified in this contract, including routines and object code libraries developed by Developer.

III. Duties

Developer shall create a computer program and related documentation (program) for Raya as per the specifications set forth in the document attached to this contract, which is incorporated by reference herein.

IV. Ownership

Program is a work made for hire. Raya shall be considered the author of Program under the U.S. Copyright laws. The Program shall be the exclusive property of Raya.

Consistent with Developer's recognition of Raya's complete ownership rights in Program, Developer agrees not to use Program or any part of it, except for the material described in Section VII of this agreement, for the benefit of any party other than Raya.

Software Development Tools purchased or developed by Developer shall remain the property of Developer.

Raya is granted the exclusive right to use and modify any of the Developer's Software Development Tools for the sole purpose of modifying and compiling the Program. Raya cannot distribute any Software Development Tools to other parties without written approval from Developer.

V. Completion Date

Developer agrees to complete all work as per the schedule set forth in the document attached to this contract, which is hereby incorporated by reference herein. This agreement shall terminate upon completion of the work as per the attached schedule and specifications.

VI. Trade Secrets

Developer understands that Raya considers all programming to be a trade secret belonging to Raya. Developer, therefore, will neither divulge nor discuss with third parties matter relating to programs on which Developer is working or any other programs belonging to Raya without written permission of Raya. In addition, Developer agrees to sign, upon request, any reasonable nondisclosure agreements relating to any aspect of Raya's business. These obligations are perpetual and shall survive any termination of this agreement. Developer acknowledges that the payments earned as per the attached schedule are adequate consideration for all his duties under this agreement, including those in paragraph VI.

Upon publication of Program, Developer shall be free to include Program in his portfolio for demonstration.

VII. Mediation and Arbitration

If any dispute arises under the terms of this agreement the parties agree to select a mutually agreeable, neutral third party to help them mediate it. If the mediation is unsuccessful, the parties agree that the dispute shall be decided by binding arbitration under the rules issued by the American Arbitration Association. The decision of the arbitrator shall be final. Costs and fees (other than attorneys' fees) associated with the mediation or arbitration shall be shared equally by the parties. Each party shall be responsible for his or her Attorneys' fees associated with arbitration.

VII. General Provisions

A. Developer may neither subcontract nor hire persons to aid in the programming work without the prior written consent of Raya, not to be unreasonably withheld.

B. Any modifications to this agreement must be in writing and signed by both parties.

C. Developer is a subcontractor to Raya and not an employee.

_____ _____

Steve Brown Date
President, Raya Systems, Inc.

_____ _____

Jay Clark Date

SCULPTURED · SOFTWARE · INC.

June 8, 1992

Mr. Steve Brown
President
Raya Systems, Inc.
2570 West El Camino Real, Suite 309
Mountain View, CA 94040

Dear Steve:

I have enjoyed working with you on the Captain Novolin project for children with diabetes, and I look forward to working with you on more health related educational video games to be published by Raya Systems. Our development team enjoys the idea of finally creating something that can directly help kids.

As one of the most active developers of games for the Super Nintendo Entertainment System, Sculptured Software is currently doing major entertainment industry contracts for Acclaim, Lucasfilm, Parker Brothers, and Nintendo directly.

Some of our recent Super Nintendo titles are:

Super WWF Wrestlemania (#1 selling Nintendo title this year)
Roger Clemens MVP Baseball
The Simpsons
Super Star Wars
Monopoly
Clue
NCAA Basketball (chosen to be published by Nintendo themselves)

We turn away dozens of game contracts each month, but we are particularly motivated to work with you on your projects because they are for a good cause, and they give us some diversity from our other projects. Frankly, we see Captain Novolin as the tip of a major iceberg.

Sincerely,

George C. Metos
President
Sculptured Software, Inc.

GCM/kep

(801) 467-2310 Fax (801) 467-2905 3269 S. Main Street, Suite 270 • Salt Lake City, Utah 84115

June 16, 1992

Dr. Norbert Jersch
Patient Systems
Boehringer Mannheim GmbH
Sandhoferstr. 116
6800 Mannheim 31

Via fax: (011 49 621) 759 4179

Dear Norbert,

To follow is the timeline that Todd and I have been working from since it was agreed upon in Budapest on March 14 and confirmed later that month.

I hope to continue development on this schedule, but I am very concerned that commitments are being made about demonstrations, evaluations and product launch without my knowledge. There is virtually nothing we can do for June 25 because we have the ADA in San Antonio. We have promised to send an updated version of Diabcare the following week.

I have added experienced staff to the Diabcare project since the Budapest meeting. Everyone on the project is very committed and working overtime to get the job done. It is not a trivial program but is complex and full-blown networking database and analysis software with many special considerations to accommodate many different needs and perspectives.

The key problem since the beginning of Diabcare which continues today is that Raya Systems has the responsibility to develop the software, but no authority to make decisions about it. The result is that we often find ourselves stuck and the progress is slower than it could be. This is not true with our other projects.

Raya Systems has already sold 10,000 copies of our educational Nintendo software and it will be in every U.S. hospital by the end of the year. With this broad customer base using computers for diabetes we are in an ideal position to step into data management. We hope to have the chance to work with you to integrate our educational products with data management and outcome evaluation programs such as Camit and Diabcare as a means to achieve the first diabetes data management with wide acceptance and use.

[redacted]

Sincerely,

Steve Brown

rayasystems

Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040
phone: (415) 949-3933
fax: (415) 949-3935

June 18, 1992

Dr. Klaus Piwernetz
DIABCARE Office
Ledererstr. 10
D-8000 München 2

Via Fax: (011 49 89) 298375

Dear Klaus:

To recap what we discussed on the phone today, I want to avoid at all costs delaying the already tight timeline of the complex Diabcare program, but I agree with you that it is also critical to support the simpler tools which will allow you to continue your work with the basic information sheet.

As a solution to our predicament I have hired a contractor who is an expert in dBase applications to provide you with the conversion tools to ensure that your Basic Information Sheet database (the "flat file") can be transferred back and forth with Diabcare.

We provided you with a conversion program in April for converting the flat file to Diabcare. Please be as explicit as possible in identifying the conversion errors, because it is often difficult for us to recognize the errors without your expertise. As you suggested, we are checking the conversion algorithm for eyes and feet complications. If there are any other errors, please let me know as soon as possible.

In order to test the conversion utilities it is essential that we get the following items as soon as possible:

1. Your 4000 record flat file. Using dummy data alone we can not duplicate the errors.

2. A Diabcare database suitable for testing the conversion from Diabcare to flat file.

3. An updated description of the fields in the flat file you are using

rayasystems

Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040
phone: (415) 949-3933
fax: (415) 949-3935

Attached to this fax, I am sending you the description of the table mapping from the flat file to Diabcare. Please note the conversion algorithms, because when the conversion is not direct, we are open to errors that are difficult to trace. I must make sure that our understandings are consistent.

If we get the information from you, I should be able to send you an updated conversion program in Oslo, hopefully with the conversion working in both directions. I have delayed my flight to the San Antonio until Friday. You can contact me during the ADA at the following address:

Marriott Rivercenter
101 Bowie Street
San Antonio, Texas 78205
phone (512) 223 1000
fax (512) 223 6239

Sincerely,

Steve Brown
President
Raya Systems

CC: Norbert Jersch. Boehringer Mannheim

raya systems

Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040
phone: (415) 949-3933
fax: (415) 949-3935

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

2392

EXHIBIT P
PAGE 1 OF 8

July 28, 1992
Invoice 59796 Page 1

RAYA SYSTEMS
2570 W EL CAMINO REAL
SUITE 309
MT VIEW CA 94040

Our File #C6228-009 For Services Through 06/22/92
Corporate

06/16/92 Telephone call to C.Godward regarding Corp.records;Review documents;organize file.
KMM 3.80 hrs.

06/17/92 Organize/set up files;Review contracts; Preparation of indexes;Telephone call from C.Godward.
KMM 3.40 hrs.

06/18/92 Review documents;Organize files;Office conference with JVD.
KMM 2.20 hrs.

Fees for legal services.....$ 611.00

Total fees and costs.....$ 611.00

Our File #C6228-006 For Services Through 06/22/92
Diabetes - Contract

06/10/92 Reply to objections to our proposed contract.
RB 3.00 hrs.

06/11/92 NNAS contract revisions & Preparation of Letter to Novo regarding sam.
RB 4.30 hrs.

06/12/92 Dictate Letter to Novo regarding contract;Telephone call S.Brown;Revise Letter per Brown;Review Letter to Mikkelson
RB 2.00 hrs.

06/12/92 ReDraft & fax Letter to Mikkelson
RB 3.50 hrs.

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

July 28, 1992
RAYA SYSTEMS Invoice 59796 Page 2

06/13/92 Review contract pursuant to Telephone conference with S.Brown;Revise attachements;Review of old contract
RB 2.00 hrs.

06/13/92 Review Letter to NNAS to ensure incorp of concerns;Drafting of Letter to Brown;
RB 2.00 hrs.

06/13/92 Drafting of second letter to NNAS;fax letters & contract
RB 1.60 hrs.

06/15/92 Telephone call from Steve regarding pricing clauses & other final details of NNAS;
RB 1.30 hrs.

06/15/92 Preparation of Letter to S.Mikkelson;Review attachment C
RB 1.00 hrs.

06/17/92 Office conference ADM regarding NNAS contract;Review Correspondence & modifications w/NNAS;Memorandum to file & ADM
RB .60 hrs.

06/22/92 Review proposed NNAS contract.
DSO .20 hrs.

06/22/92 Review proposed ammend to NPPI contract;Review orig NPPI Agreement & compare; Office conference DSO regarding same
RB .60 hrs.

Fees for legal services.....$ 2007.00

ADVANCED COSTS

Postage/Telecopy	$	17.97
Telephone Charges	$	13.33
Photocopies	$	9.00

Total Costs.....$ 40.30

Total fees and costs.....$ 2047.30

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

Our File #C6228-010 For Services Through 06/22/92
Intellectual Property

ADVANCED COSTS

Photocopies	$	10.80
Total Costs.....	$	10.80
Total fees and costs.....	$	10.80

Our File #C6228-001 For Services Through 06/22/92
Miscellaneous

05/26/92	Review Letter from former counsel of S.Brown regarding release of files.	
	RB	.50 hrs.
05/27/92	Telephone calls to Cooley;Preparation of Letter to Cooley regarding file release.	
	RB	.80 hrs.
06/01/92	Review billing Memorandum.	
	RB	.20 hrs.
06/11/92	Revise Medical Director Agreement per Letter.	
	JVD	1.00 hrs.
06/13/92	Reorganize Raya file according to new projects.	
	RB	.50 hrs.
06/15/92	Office conference with RB regarding case background,record organization & maintenance of files.	
	KMM	2.10 hrs.
06/15/92	Office conference KMM regarding file organiztion	
	RB	.30 hrs.

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

06/16/92 Telephone conference with DSO regarding new confidentiality contract;Office conference ADM re same
RB .20 hrs.

06/17/92 Drafting of employment confidentiality contract.
RB 1.40 hrs.

06/17/92 Check Calif. statute regarding limits on employee confidentiality Agreements.
ABL .90 hrs.

06/18/92 Review employee confidentiality draft.
ADM .90 hrs.

Fees for legal services.....$ 747.50

ADVANCED COSTS

Postage/Telecopy	$	167.99
Telephone Charges	$	195.51
Photocopies	$	216.20
Word Processing	$	418.00
Lexis Computer Usage	$	13.23

Total Costs.....$ 1010.93

Total fees and costs.....$ 1758.43

Our File #C6228-007 For Services Through 06/22/92
Nintendo - Contract

06/01/92 Work on addendum to Nintendo contract.
RB .60 hrs.

Fees for legal services.....$ 54.00

ADVANCED COSTS

Photocopies	$	6.20

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

July 28, 1992
RAYA SYSTEMS Invoice # 59796 Page 5

Total Costs.....$ 6.20

Total fees and costs.....$ 60.20

Our File #C6228-002 For Services Through 06/22/92
PCSL (Verlag) Contract

06/01/92 Work on new Europe game.
RB .80 hrs.

06/08/92 Review draft contract for AIDS game;Suggest revisions.
DSO .30 hrs.

06/08/92 Review Letter of understanding faxed from Steve;Telephone calls to Steve regarding contract regarding AIDS
RB 1.50 hrs.

06/08/92 dictate Letter for Steve<s Review
RB 1.50 hrs.

06/09/92 Preparation of Letter to S.Brown regarding DSO<s comments on AIDS contract;
RB 1.80 hrs.

06/09/92 Telephone calls to/from Steve Brown;Drafting of Letter
RB 1.80 hrs.

Fees for legal services.....$ 720.00

Total fees and costs.....$ 720.00

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

July 28, 1992
RAYA SYSTEMS Invoice 59796 Page 6

Our File #C6228-003 For Services Through 06/22/92
Smoke - Contract

05/26/92	Office conference with DSO regarding modifications to sculptured contract.	
	RB	.20 hrs.
05/26/92	Office conference with TNM regarding contract clause:Redraft modifications.	
	RB	1.00 hrs.
05/26/92	Telephone call to S.Brown & incorp. revisions;Prepare Letter to S.Brown.	
	RB	1.50 hrs.
05/26/92	Review final contract;Preparation of Letter to G.Metos regarding same;Fax to S.Brown.	
	RB	1.50 hrs.
05/26/92	Conference regarding sculptured contract provisions.	
	TNM	.10 hrs.
05/26/92	Edit contract with Sculptured.	
	DSO	.40 hrs.
05/27/92	Telephone call from Steve regarding sculptured contract changes.	
	RB	.70 hrs.
05/27/92	Review Letter from Steve / Letter to Steve regarding DSO's comments on contract.	
	RB	1.00 hrs.
05/28/92	Review final Sculptured contract;Telephone call to S.Brown.	
	RB	.60 hrs.
06/01/92	Telephone conference with Steve regarding negotiations regarding contract modification.	
	RB	1.00 hrs.

OLES, MORRISON & RINKER
LAWYERS
ACCOUNTING DEPT. 3011
P.O. BOX 34936
SEATTLE, WASHINGTON 98124-1936
(206) 623-3427

FEDERAL ID NO. 91-0574243

July 28, 1992
Invoice 59796 Page 7

RAYA SYSTEMS

06/01/92 Review & Revise medical director Agreement as per Steve's instructions.
RB 1.80 hrs.

06/10/92 Letter to Dr. Taylor.
RB 1.70 hrs.

Fees for legal services.....$ 1074.50

ADVANCED COSTS

Photocopies $ 5.20

Total Costs.....$ 5.20

Total fees and costs.....$ 1079.70
PLEASE REMIT TOTAL BALANCE DUE.....$ 6287.43

This invoice may not include expense items for which we have not yet been billed

RAYA SYSTEMS, INC.
2570 W. EL CAMINO REAL #309
MOUNTAIN VIEW, CA 94040

BANK OF AMERICA NT & SA
SAN ANTONIO BRANCH 0448
P.O. BOX 340
MOUNTAIN VIEW, CA 94042
11-35/1210

2392

17 Aug 92

Pay to the Order of Oles, Morrison & Rinker $****6,287.43

ix Thousand Two Hundred Eighty-Seven and 43/100********** Dollars

Oles, Morrison & Rinker
Lawyers
Accounting Dept. 3011
P.O. Box 34936
Seattle, Washington 98124-1936

memo

⑈002392⑈ ⑆121000358⑆ 04482⑈15097⑈ ⑈0000628743⑈

EMERSON BROOKS AND ASSOCIATES, INC.

6500 WILSHIRE BLVD SUITE 1960
LOS ANGELES, CALIFORNIA 90048
TEL 213 852 9600
FAX 213 852 4747

June 25, 1992

Mr. Steve Brown
Raya Systems
2570 West El Camino #309
Mountain View, California 94040

Dear Mr. Brown,

As we discussed, Emerson Brooks and Associates, Incorporated agrees to charge a flat fee of Five Thousand ($5,000.00) dollars, for the placement of Mr. Jack Thornton only.

Emerson Brooks also agrees to a Thirty (30) calendar day unconditional guarantee, and a Thirty-one (31) to Ninety (90) calendar day guarantee, pro-rated on a daily basis, for Mr. Thornton.

Terms of payment shall be One-third (1/3) net Thirty (30) days, One-third (1/3) net Sixty (60) days, and (1/3) net Ninety (90) days from Mr. Thorton's start date.

Should you have any questions, please feel free to contact me at your convenience.

Sincerely,

Jeffrey P. Brunner
Software Engineering Division

JB/lc

Agreed:_____
Mr. Steve Brown

Date:_____

#2393

EMERSON BROOKS AND ASSOCIATES, INC.

6500 WILSHIRE BLVD SUITE 1960
LOS ANGELES, CALIFORNIA 90048
TEL 213 852 9600
FAX 213 852 4747

DATE: June 30, 1992

INVOICE # 2493
Client # 1321

Raya Systems
2570 West El Camino Suite 309
Mountain View, California 94040

Attn: Mr. Steve Brown
Software Manager

FOR SERVICES RENDERED IN THE PLACEMENT OF: Mr. Jack Thornton

START DATE: ~~July 1, 1992~~ July 23

Standard Fee	$16,500.00
Less Discount	11,500.00-
Less Second Invoice	1,666.67-
Less Third Invoice	1,666.66-
Net Due:	$1,666.67

Aug 23

TERMS OF PAYMENT ARE NET DUE FIVE THOUSAND ($5,000.00) DOLLARS. THE FIRST PAYMENT OF ONE THOUSAND, SIX HUNDRED, SIXTY-SIX DOLLARS AND SIXTY-SEVEN CENTS ($1,666.67) IS DUE ON OR BEFORE ~~JULY 30, 1992.~~ THE SECOND PAYMENT OF ONE THOUSAND, SIX HUNDRED, SIXTY-SIX DOLLARS AND SIXTY-SEVEN CENTS ($1,666.67) IS DUE ON OR BEFORE ~~AUGUST 29, 1992~~. THE THIRD PAYMENT OF ONE THOUSAND, SIX HUNDRED, SIXTY-SIX DOLLARS AND SIXTY-SIX CENTS ($1,666.66) IS DUE ON OR BEFORE ~~SEPTEMBER 28, 1992.~~ Sep 23 Oct 23 GUARANTEE EXPIRES ON SEPTEMBER 28, 1992.

THIS IS THE FIRST OF THREE (3) INVOICES.

RAYA SYSTEMS, INC.
2570 W. EL CAMINO REAL #309
MOUNTAIN VIEW, CA 94040

BANK OF AMERICA NT & SA
SAN ANTONIO BRANCH 0448
P.O. BOX 340
MOUNTAIN VIEW, CA 94042
11-35/1210

2393

17 Aug 92

Pay to the Order of Emerson Brooks and Associates, $****1,666.67

One Thousand Six Hundred Sixty-Six and 67/100********** Dollars

Emerson Brooks and Associates,
Inc.
6500 Wilshire Blvd Suite 1960
Los Angeles, CA [illegible] 5519 050

826920000088103248

memo

⑈002393⑈ ⑆121000358⑆ 0448 2⑈ 15097⑈ ⑈0001666667⑈

BUSINESS SERVICES
PAYROLL SERVICE

PAYROLL EARNINGS REGISTER

DC-88 BPR | COMPANY NUMBER 53148 | PAYROLL NUMBER 61 | HOME DEPT. NUMBER 1 | RAYA SYSTEMS INC | PAYROLL PERIOD ENDING DATE 6-30-92 | PAGE 1 | REPORT DATE 6-26-92 | APPL CTR 1 | YEAR SF 1992

	EMPLOYEE NAME / EMPLOYEE NO. SOC. SEC. NO.	DATE OF LAST PAY	M S	FIT SEX	DIST EX	CURRENT REGULAR UNITS	CURRENT REGULAR PAY	CURRENT OVERTIME EXPENSE UNITS	CURRENT OVERTIME EXPENSE PAY	CURRENT GROSS EARNINGS W-2 PAY YEAR TO DATE	CURRENT WITHHOLDS F.I.T.	F.I.C.A.	S.I.T.	D.I.	OTHER	CURRENT VOLUNTARY DEDUCTIONS 1.DECLRD TIPS YTD 2.OTHER COMP. YTD	EXCLUDABLE YTD MEALS/LODG	NET PAY
	YEAR TO DATE WITHHOLDS																	
1	BAKER, AARON J.	00 05		S	01	100												
2	BLUM, A. JIM	00 05		S	05	100												ADJMT 1
3	BLUM, A. JIM	00 05		S	05	100												
4	BOUYSSOUNOUSE, EMANUEL	604 05		S	02	100												
5	BROWN, STEPHEN J.	604 05		S	02	100												
6	KHATSET, NATALIE	00 05		M	08	100												
7	NOVAK, LOUISE C.	604 05		S	02	100												
8	RAMMING, TODD A.	604 05		S	02	100												
9	SCHEURKOGEL, PATRICIA	00 05		S	02	39												
10	THORNTON, JACK L.	00 05		S	06	100												
11	WEHNER JR., JAMES P.	604 05		S	01	100												
12																		
13	DEPARTMENT TOTALS- NO. OF EMPLOYES 10					1039												
14	FUTA TAX 139.84 / SUI TAX 454.48												CO.FICA				ADJ.	
15							DEPARTMENT		2									
16	LUM, GERARD T.	604 05		S	02	100												
17																		
18	DEPARTMENT TOTALS- NO. OF EMPLOYES 1					100												
19	FUTA TAX .00 / SUI TAX .00												CO.FICA					
20																		
21																		
22																		
23																		
24																		
25																		
26																		

EXHIBIT Q
PAGE 4 OF 5

Employee Master Information 1992

Employee	1992 Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Ame, Clarice	[redacted]												
Baker, Aaron	[redacted]												
Blum, Ira	[redacted]												
Bouyssonmouse, Emanuel	[redacted]												
Brown, Steve	[redacted]												
Gaxiola, Gina	[redacted]												
Gemeny, Beth	[redacted]												
George, Jeff	[redacted]												
Hall, Hope	[redacted]												
Khatset, Natalie	[redacted]												
Kobayashi, Hael	[redacted]												
Lum, Gerard	[redacted]												
Montemar, Beth	[redacted]												
Novak, Louise	[redacted]												
Porter, Cheri	[redacted]												
Ramming, Todd	[redacted]												
Renshaw, Cheryl	[redacted]												
Roathe, Lane	[redacted]												
Scheurkogel, Patty	[redacted]												
Thornton, Jack	[redacted]												
Wehner, Jim	[redacted]												
Williams, Art	[redacted]												
	[redacted]												

EXHIBIT Q
PAGE 5 OF 5

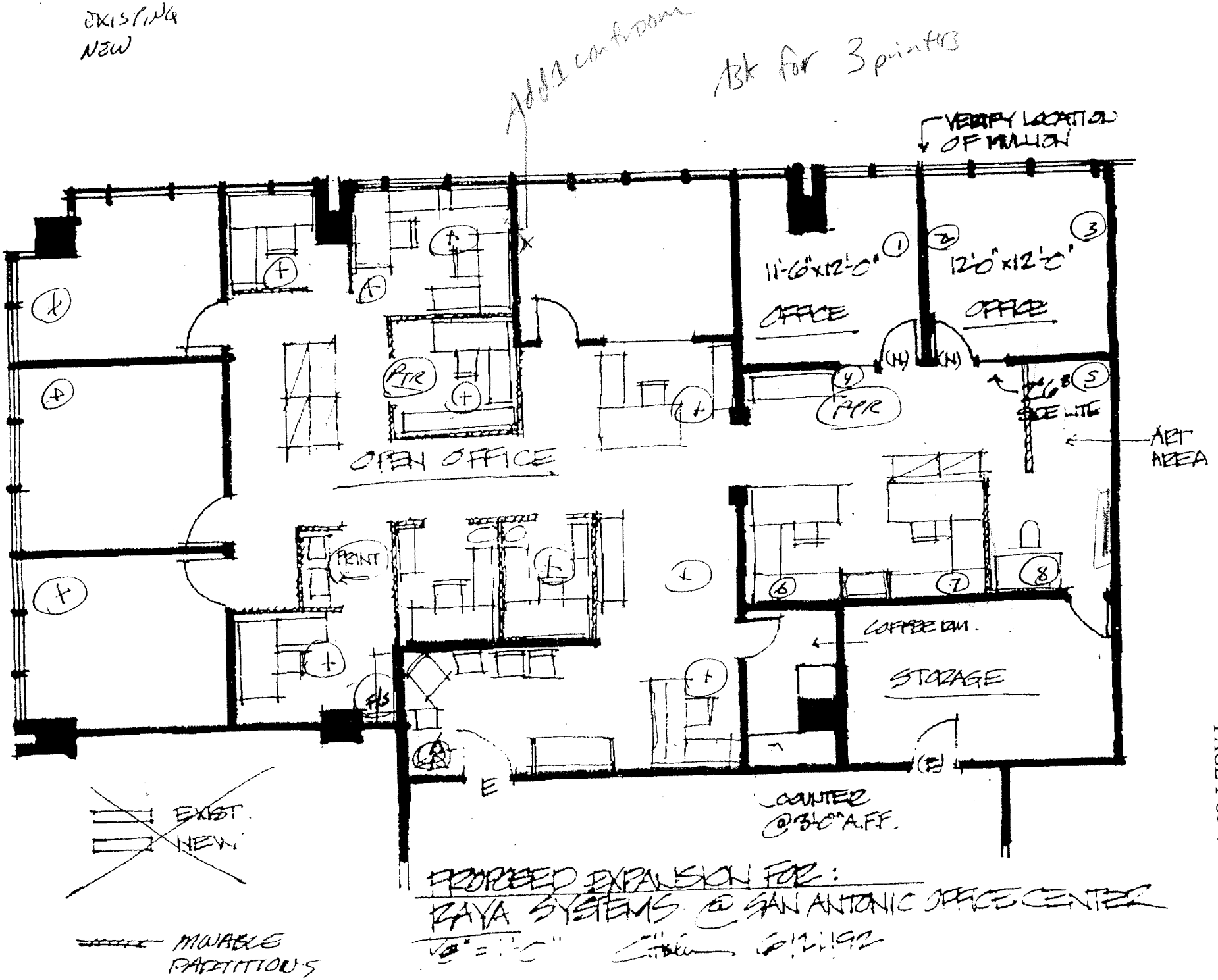
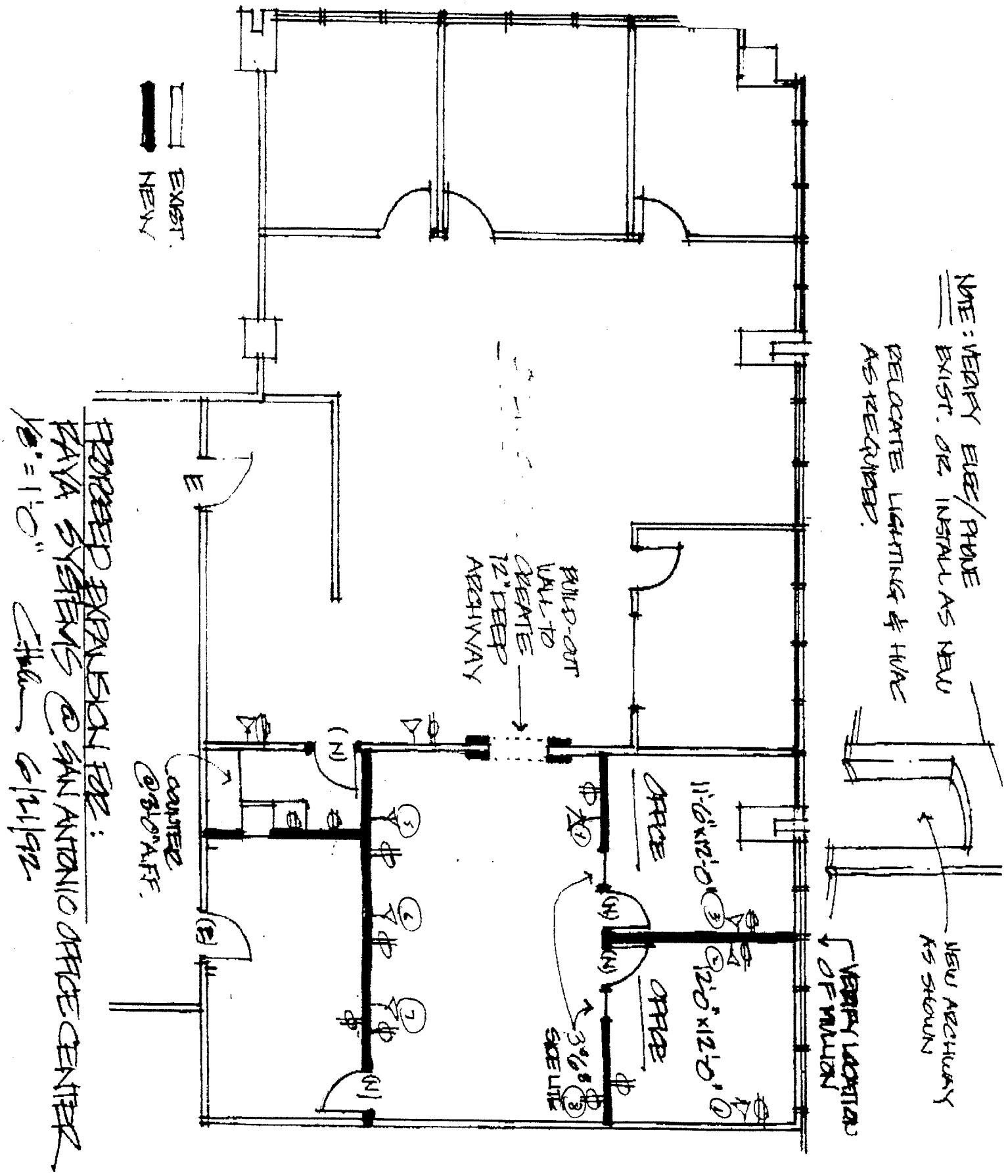


EXHIBIT R
PAGE 1 OF 4

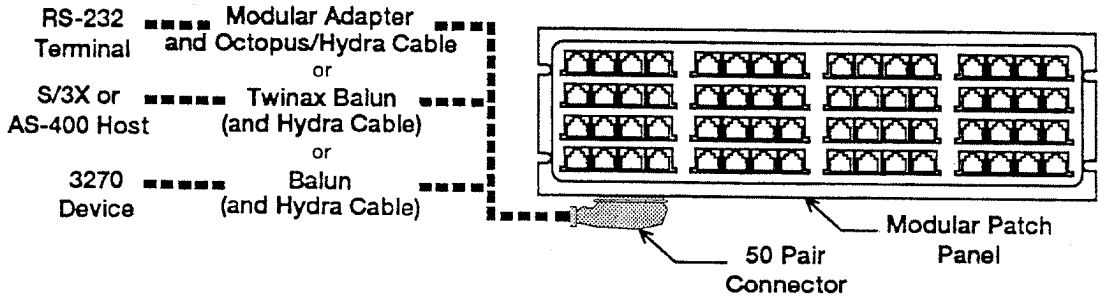

EXIST.
NEW
NOTE: VERIFY ELEC/PHONE EXIST. OR INSTALL AS NEW
RELOCATE LIGHTING & HVAC AS REQUIRED.
BUILD-OUT WALL TO CREATE 12" DEEP ARCHWAY
11'-0" x 12'-0" OFFICE
12'-0" x 12'-0" OFFICE
3'-0" SIDE LITE
VERIFY LOCATION OF MULLION
NEW ARCHWAY AS SHOWN
COUNTER @ 36" A.F.F.
REVISED EXPANSION FOR: PAYA SYSTEMS @ SAN ANTONIO OFFICE CENTER
1/8" = 1'-0"
6/24/92

PC Board Distribution Patch Panel

Using standard telecommunication components, the panel converts a 25-pair (50-pin) connector into a cluster of modular RJ11 or RJ45 jacks. Each jack is numbered to correspond to host or terminal ports. Each of the 25 twisted pair cables can contain either 3270-type data terminals from a single controller (up to 24 terminals per cable), twinax data links (up to eight per cable), or RS232C ports (up to eight per cable).

Localized cross-connecting and circuit rearrangements are accomplished by patching modular line cords from one jack to another. The result is increased flexibility and a reduction of costly downtime by providing a bypass in the event of equipment failure.

NEVADA WESTERN PC Board Distribution Patch Panel

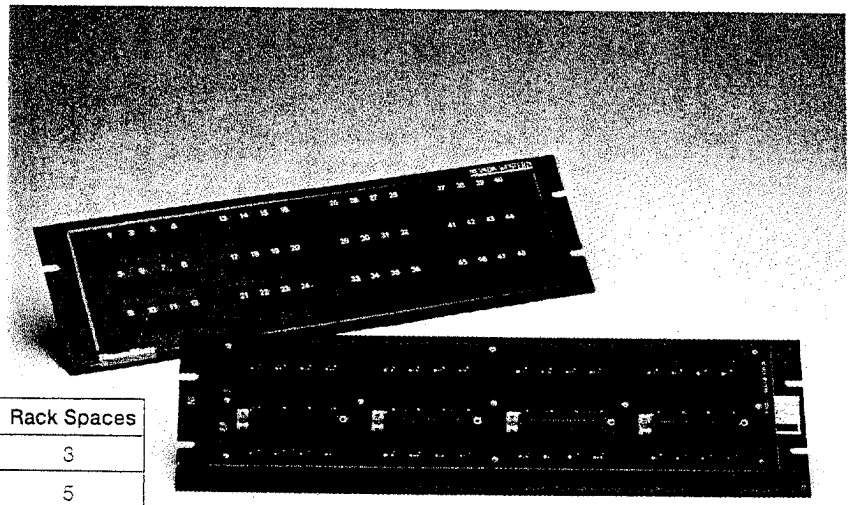


Specifications

Dimensions: 24-port: 19" w, 1 1/2" d, 1 3/4" h
48-port: 19" w, 1 1/2" d, 5 1/4" h
96-port: 19" w, 1 1/2" d, 8 3/4" h

Data rate: 4 Mbps

Environment: 3X74 — distribution
RS232C — distribution
Twinax — distribution
Voice/PBX — distribution



Catalog Number

Wiring Series	No. Ports	Catalog Number	Rack Spaces
1000-2 wire	48	023-1000-48-2P	3
	96	023-1000-96-2P	5
1000-4 wire	48	023-1000-48-4P	3
	96	023-1000-96-4P	5
1000-6 wire	48	023-1000-48-6P	3
	96	023-1000-96-6P	5
1300-4 wire	24	023-1300-24-4P	1
2000-8 wire	48	023-2000-48-8P	3
	96	023-2000-96-8P	5
8000-8 wire	48	023-8000-48-8P	3
	96	023-8000-96-8P	5

For ordering or other information, please call our Regional Sales Offices:

Western Region (800) 828-9287
Midwest Region (800) 247-5370
Eastern Region (800) 542-6859

NEVADA WESTERN
A Subsidiary of Thomas & Betts Corporation
615 North Tasman Drive
Sunnyvale, CA 94089-1950
(408) 734-2700

Thomas&Betts

JUL 06 '92 12:56 HANSEN BROS CONSTR 408 7357109

HANSEN BROS.

Construction Specialties, Inc., 2273 De La Cruz Blvd., Santa Clara, CA 95050, License No: 435395, Phone: 408/727-2777, FAX: 408/727-1161

July 7, 1992

Raya Systems
2570 West ElCamino Real # 309
Mouuntain View, CA 94040

Attn.: Ms. Louise Novak

Reg.: Tenant Improvement.

Dear Ms. Novak,

Thank you for the opportunity to give the following price quotations. Based on your instructions and your 1 pc. drawings:

1. Build new walls per owners plan.
2. Install 15 new electrical power outets and provide 10 wall cut and box for telephone, per drawing. Provide and install six new 2x4 light fixtures and wall switching (8 total). Change two existing single switches to 3 way switches.
3. Provide three new doors and frames. Hardware passage lever.
4. Provide and install two 5.0 x 6.8 windows aluminum frame, tempered glass per code.
5. Paint (standard) new office areas. Sand and refinish entry door.
6. Demo existing carpet and install new carpet and rubber base to match carpet in suite 309.
7. Fabricate new reception counter; L-shape with two colors and design on front panel to simulate arch in new opening.
8. Clean up & supervision.

TOTAL PROJECT COST ..... $ 18,789.00

N.I.C.: Plans, permits, fees. Moving equipment and furniture

All work to be done to all state and local codes.

Ed Iglesias
Estimator/Project Manager

...KETING DEPARTMENT
...ES CARE DIVISION
...LEFAX + 45 42 98 58 00

NO
DK
TELEPHON...

Page: 1 of: 1

To: Steve Brown
Raya Systems

Fax No: 009 1 415 949 3935

From: Liz Dempsey Becker

Date: July 2, 1992

cc.: SKHa

Dear Steve:

Congratulations on the overwhelming success of Captain Novolin! Obviously it was the major news from the ADA this year. I hope you are as pleased with the feedback as is Novo Nordisk.

As mentioned to you at the conference, we are unable to plan similar exposure at EASD because we are launching a new product and focusing on our R&D projects. However, with those affiliates that take Captain NovoCare, we are urging them to do a PR campaign as was done in the US. We are collecting all the media clippings so that we can use them to "sell" the program to the affiliates.

We will only have one "play station" at our stand. Please let me know the technical specs for the hardware you believe necessary at the booth for the pc version. We must either ship the equipment by August 15 or try and rent it in Czechoslovakia (if they have it!).

For your info, all of the 7 affiliates are reviewing their packages at the moment and will return to us ASAP. I have given Louise their names so that she can contact them to move the process.

I will be moving the project along while Susanne is away so call or fax anytime.

Congratulations again!

Liz

Liz

Louise Sent fax of recommended hardware for convention 7/2/92

INTL. MARKETING DEPARTMENT
DIABETES CARE DIVISION
TELEFAX + 45 42 98 58 00

NOVO NORDISK A/S
DK 2880 BAGSVÆRD
TELEPHONE + 45 4444 8888

Page: 1 of: 1

To: Steve Brown
Raya Systems

Fax No: 009 1 415 949 39 35

From: Liz Dempsey Becker

Date: July 10, 1992

cc.: SKHa

Dear Steve:

Thanks for your fax and your suggestions for EASD. However, I think it is necessary for you to attend for many reasons. The interested doctors will most likely want to hear about how/why the game was developed and the "testing" it has been through. I'm referring here to the presentation you made at ADA. They may also have heard something about it at ADA.

In addition, a number of affiliate marketing people will be either working on the stand or attending the congress. They will be interested in meeting you to talk generally about versions for their coutnries as well as want to know more about how/when the game could be moved on to Nintendo. While I agree, working on the stand may be a bit boring, we reallly think for the above reasons that you should attend.

I hope this does not create any problems.

Liz

Liz

To: Liz Dempsey Becker
Novo Nordisk, Copenhagen
011- 45-44-44-2131

From: Steve Brown
Raya Systems
001-415-949-3935

Date: July 14, 1992

Pages: 1

Dear Liz,

I would be happy to meet with the affiliate marketing people and demonstrate Captain NovoCare to doctors at the booth, but I would not be able to work at the booth full-time, because I will need to go to some other meetings. I also may be participating in one of the presentations (still tentative). If you need someone to be there all of the time, I suggest that either two (2) people from Raya be there or that a Novo Nordisk person learn how to demonstrate the game.

I don't mind working on the stand, but I have some other obligations as well.

Sincerely,

Steve Brown

P.S. I am still waiting for a response to the contract. Erik says (and it is fine with me) that we should keep North America and The Rest of the World separate, so it needs a slight modification.

P.P.S. I heard that Susanne was confused about Conversions, Modifications, and Sequels. Those are commonly understood terms in the computer game world, but I will try to make some better definitions if she can let me know where the confusion lies.

Swissair 1042 rt
Delta 1080 rt

14 day min stay 6 days; rooms available

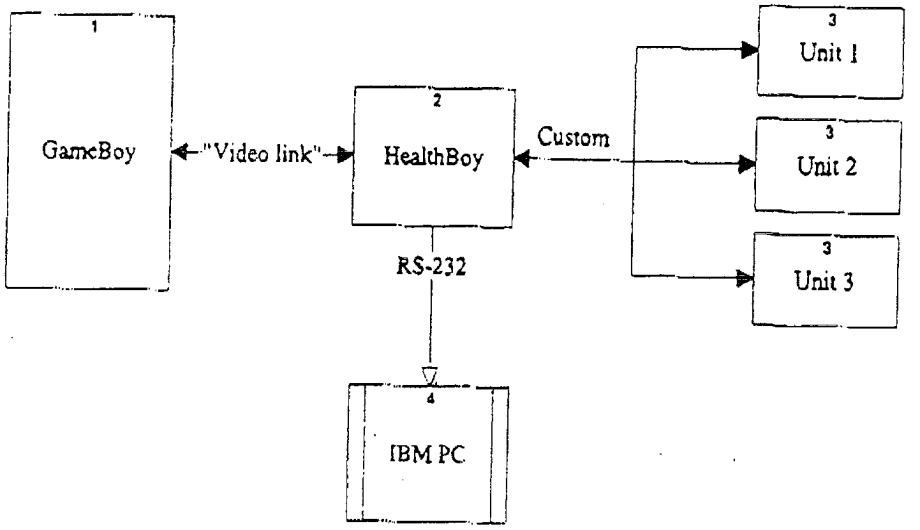
rayasystems

HealthBoy Project

TopChart

Thursday, August 13, 1992

11:46 AM



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HealthBoy features:

- *Communicate to GameBoy via serial "Video-Link" (multi-player) cable*
- *Communicate to multiple external devices (e.g. diabetes blood-sugar meter) via custom hookup*
- *Dump data to external computers (e.g. IBM PC) via RS-232 (9-pin connector)*
- *Clock/Calendar capability for time/date stamp of samples*
- *Internal battery backed-up RAM for storage of samples*
- *Low-power microprocessor*
- *Input connectors designed to be "user stupid"/hard to damage*
- *GameBoy cartridges for each external device for display of data*

Hardware wish list:

- *Microprocessor with multiple interrupt levels*
- *Hardware-driven communications with GameBoy with buffer*
- *Automatic RS-232 buffer*
- *Hardware-driven communications with external devices with buffer*
- *Large amount of RAM for long-term storage of samples*

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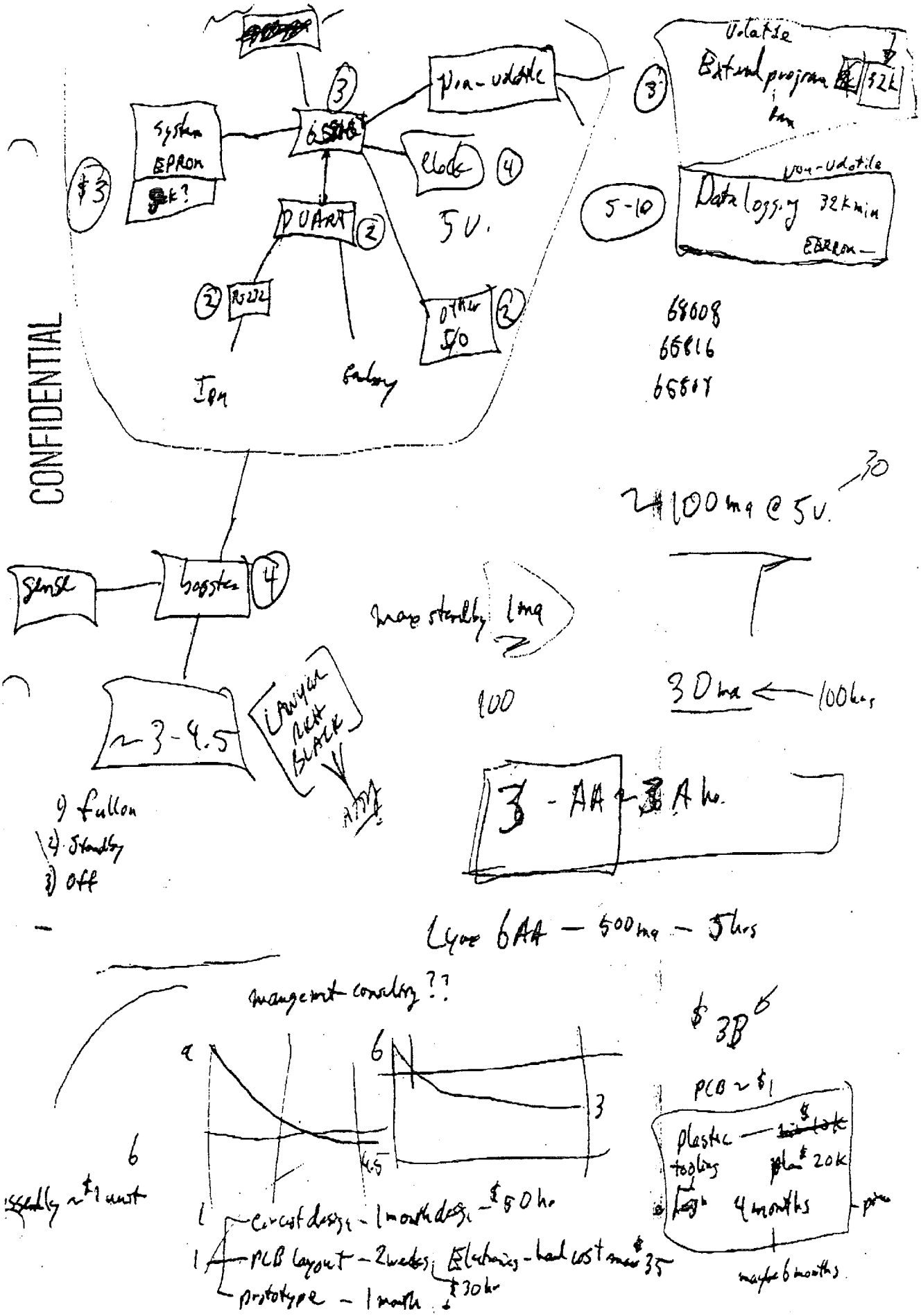

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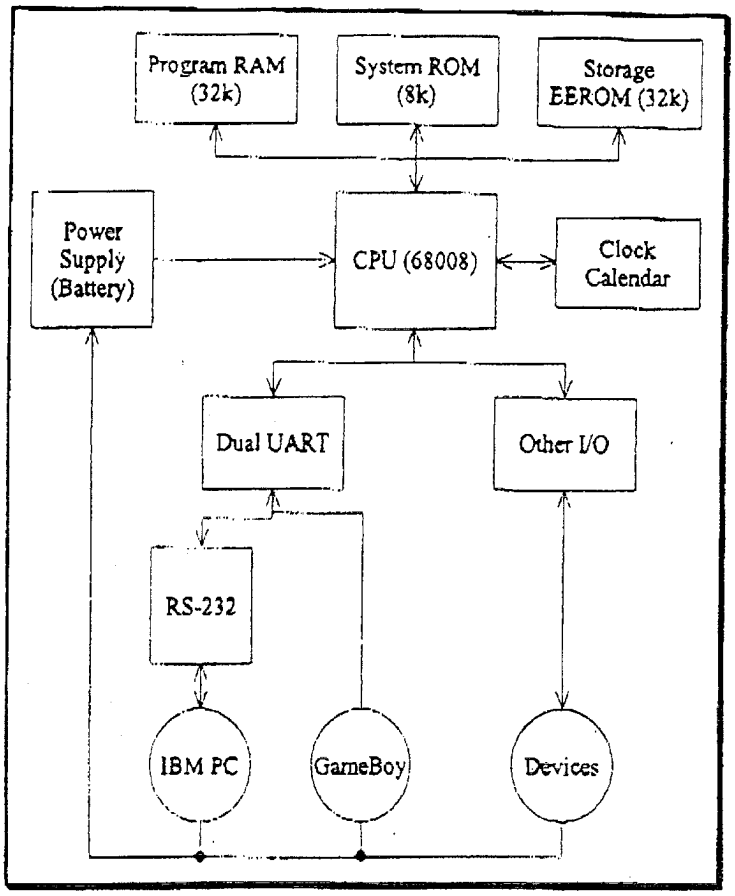

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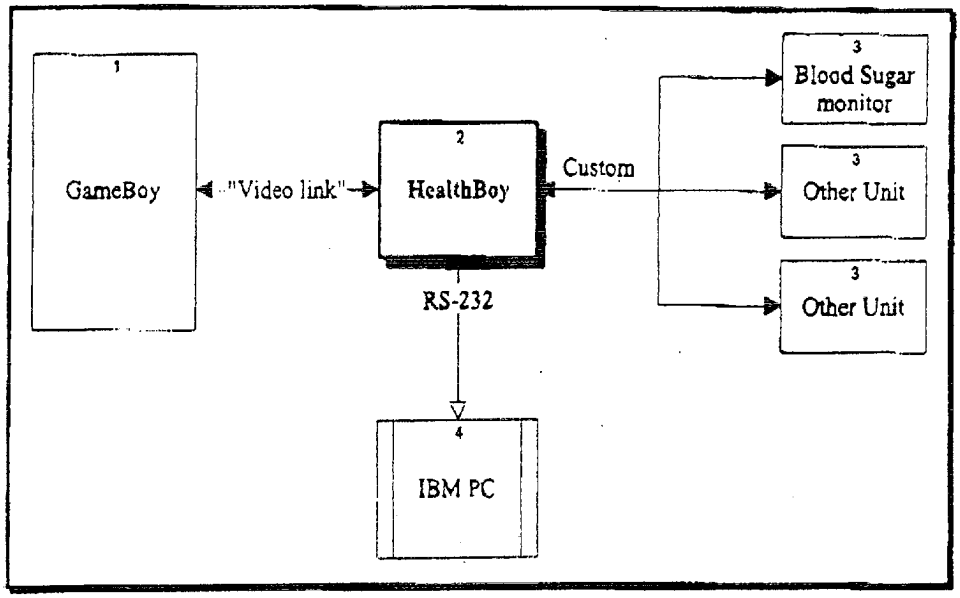
Development Cost (estimates)

Description	Units	Unit type	Rate	% use	Brdn Rate	Cost
Hardware design/test	6	weeks	$2,000.00	100%	100%	$12,000.00
Hardware prototyping	4	weeks	$800.00	100%	100%	$3,200.00
Circuit board design	2	weeks	$1,200.00	100%	100%	$2,400.00
Plastic design & development	4	months				$20,000.00
Software design	4	weeks	$1,000.00	100%	125%	$5,000.00
Software implement/test	6	weeks	$1,000.00	100%	125%	$7,500.00
Management	14	weeks	$1,084.62	10%	125%	$1,898.08
Clerical	14	weeks	$538.46	5%	125%	$471.16
Photocopy/Supplies	14	weeks	$10.00	100%	100%	$140.00
Telephone	14	weeks	$10.00	100%	100%	$140.00
Shipping						$300.00
GameBoy Develop. system						$13,000.00
IBM PC System						$2,600.00
Estimated costs						$68,549.23
Reserve (15%)						$10,282.38
Total development budget						$78,831.62

Note:
Another option is to build our own custom chip to perform most of the functions of the separate parts specified in the design.
Advantages:

Functional design / features



Basic hardware design

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rayasystems

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Non-Disclosure Agreement

This agreement is made to be effective the 13th day of August, 1992 by and between Craig Nelson and Raya Systems, Inc., 2570 West El Camino Real, Suite 309, Mountain View, CA 94040, hereinafter referred to as "PARTIES."

The "PARTIES" agree that, with respect to any confidential information disclosed by one PARTY to the other, both PARTIES will apply and honor the mutual covenants and promises described below:

(1) "Confidential Information" shall be any and all information which is in fact confidential and proprietary to the disclosing PARTY and which the disclosing PARTY designates as confidential at the time such disclosure is made;

(2) The non-disclosing PARTY shall not disclose or cause to be disclosed, in whole or in part, any such Confidential Information to any third party without the prior written consent of the disclosing PARTY, except where:

(a) at the time of disclosure, the Information is publicly known, or was already known (as evidenced by documents) by the non-disclosing PARTY, or

(b) after disclosure to a PARTY, such information becomes publicly known through no fault of the PARTIES, or

(c) disclosure is required by law or governmental agency or any subdivision thereof, or

(d) seven (7) years have elapsed from the date upon which disclosure is made;

(3) In the event that either of the PARTIES breaches this agreement, the breaching PARTY shall be liable for any and all losses resulting from said breach which are incurred by the non-breaching PARTY.

8/13/92
Date

By: Craig Nelson

8/13/92
Date

RAYA SYSTEMS, INC.

By: Jack Thornton
Director of Product Development

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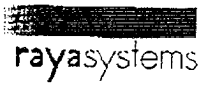
FAX LETTER



Raya Systems, Inc.
2570 West El Camino Real, Suite 309, Mountain View, California 94040
Phone (415) 949-3933 Fax (415) 949-3935

TO:	Richard T. Black
COMPANY:	Oles, Morrison & Rinker
FAX NUMBER:	(206) 682-6234
FROM:	Jack Thornton
DATE:	August 14, 1992
RE:	HealthBoy project - potential patent application
NUMBER OF PAGES:	7, including this one
CC:	Steve Brown

CONFIDENTIAL

I have been instructed by Steve Brown to forward notes about the HealthBoy project to you for the purposes of a possible patent application. I met with a hardware engineer yesterday, and based on that information I have a very preliminary design of the central module with cost estimates. Included in this fax are my notes, the engineer's (Craig Nelson's) handwritten notes, and the non-disclosure agreement signed by Craig.

As more information is developed, I will be forwarding it to you.

If you have any questions, please feel free to give me a call.

RECEIVED
8:15 am
AUG 14 1992
OLES, MORRISON & RINKER

Sincerely,

Jack Thornton
Director of Product Development
Educational Software

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- Lower per-unit cost (estimated $10 less per unit, depending on quantity manufactured at one time)
- Lower MSRP (by $50 to $80)
- Allow for addition of customized features (hardware assisted communications, etc) which increase usefulness and flexibility of the device

Disadvantages:

- Increase development time from 3.5 months to 9.5 months (additional 6 months)
- Increase development cost by about $60,000

Per-unit cost (estimates)

Description	Cost	
Hard costs (parts and connectors)	$35.00	
Circuit board	$1.00	
Plastic case	$0.50	
Assembly	$1.00	
Packaging (box, packing, instruction booklet)	$1.50	
Total estimated per-unit cost	$39.00	
MSRP range	$195.00	$312.00

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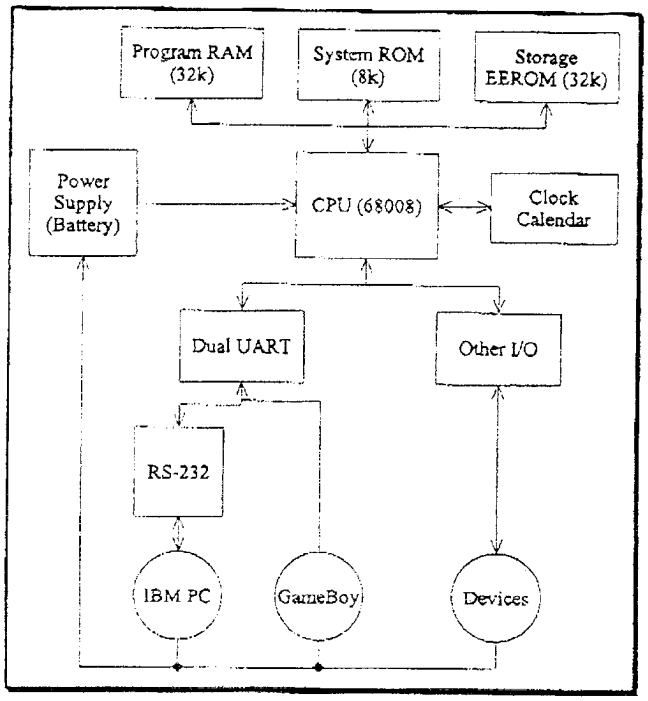

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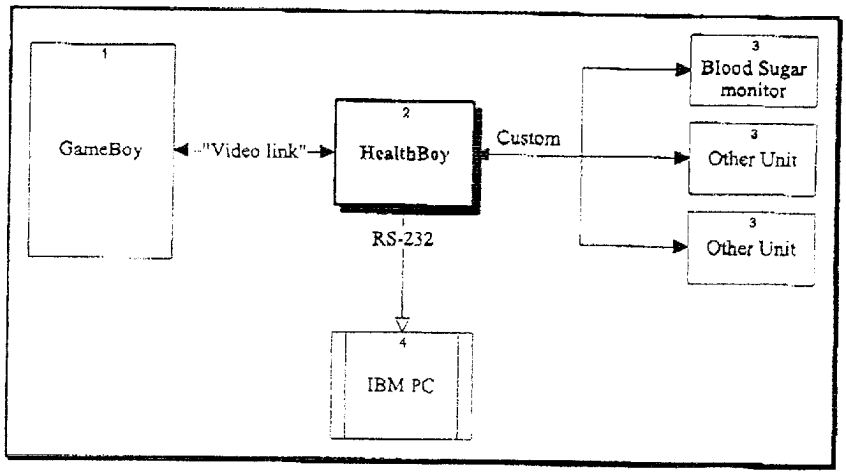

Basic hardware design

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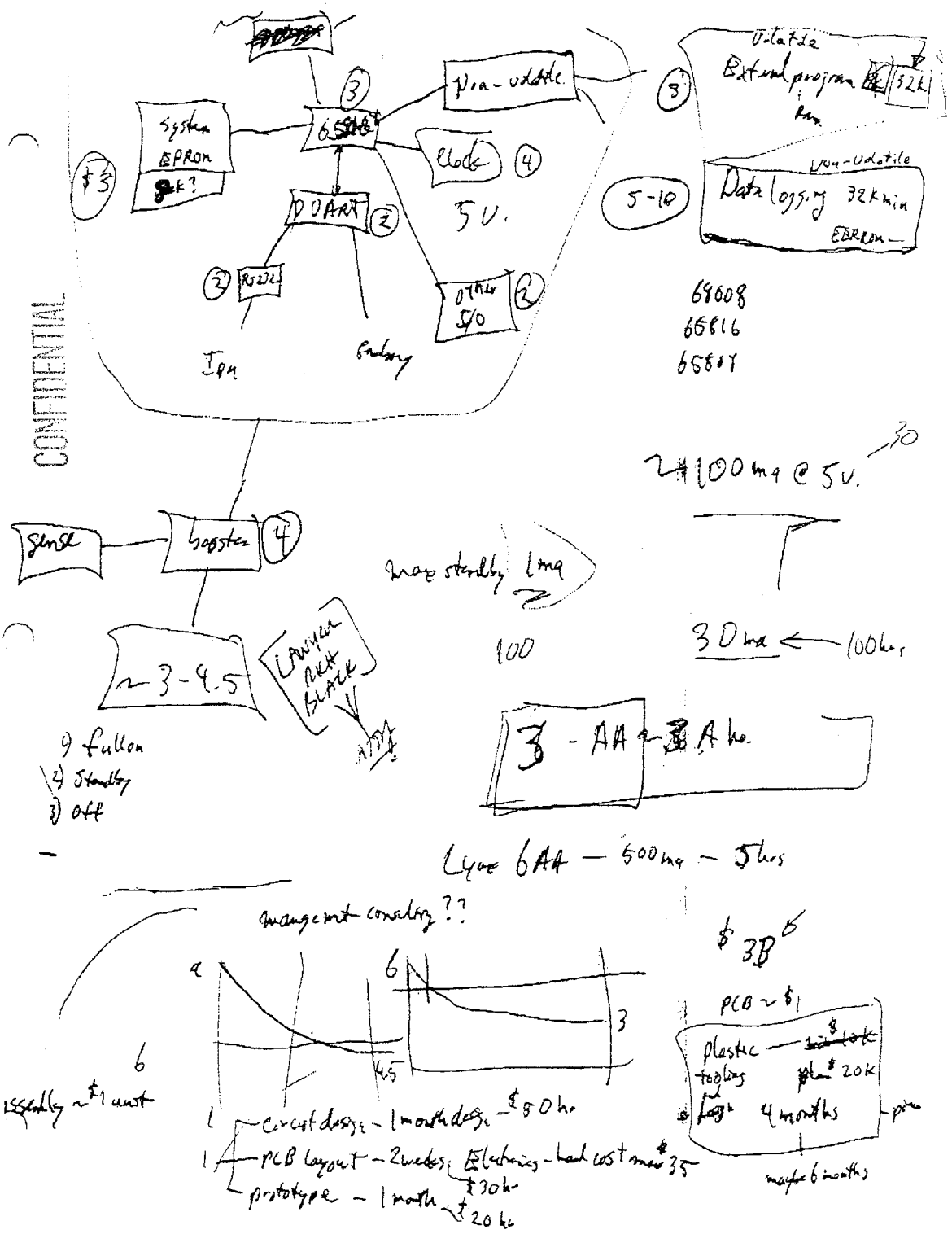

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rayasystems

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(1) "Confidential Information" shall be any and all information which is in fact confidential and proprietary to the disclosing PARTY and which the disclosing PARTY designates as confidential at the time such disclosure is made;

(2) The non-disclosing PARTY shall not disclose or cause to be disclosed, in whole or in part, any such Confidential Information to any third party without the prior written consent of the disclosing PARTY, except where:

(a) at the time of disclosure, the Information is publicly known, or was already known (as evidenced by documents) by the non-disclosing PARTY, or

(b) after disclosure to a PARTY, such information becomes publicly known through no fault of the PARTIES, or

(c) disclosure is required by law or governmental agency or any subdivision thereof, or

(d) seven (7) years have elapsed from the date upon which disclosure is made;

(3) In the event that either of the PARTIES breaches this agreement, the breaching PARTY shall be liable for any and all losses resulting from said breach which are incurred by the non-breaching PARTY.

8/13/92
Date

By: Craig Nelson

8/13/92
Date

RAYA SYSTEMS, INC.

By: Jack Thornton
Director of Product Development

CONFIDENTIAL

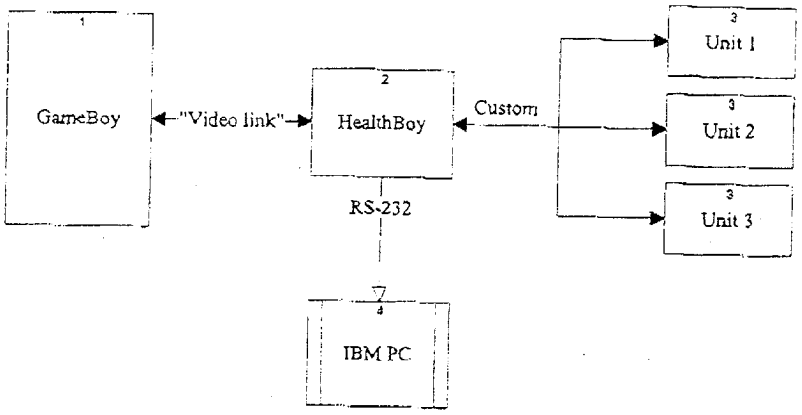
rayasystems

HealthBoy Project

TopChart

Thursday, August 13, 1992

11:46 AM



CONFIDENTIAL

HealthBoy features:

- *Communicate to GameBoy via serial "Video-Link" (multi-player) cable*
- *Communicate to multiple external devices (e.g. diabetes blood-sugar meter) via custom hookup*
- *Dump data to external computers (e.g. IBM PC) via RS-232 (9-pin connector)*
- *Clock/Calendar capability for time/date stamp of samples*
- *Internal battery backed-up RAM for storage of samples*
- *Low-power microprocessor*
- *Input connectors designed to be "user stupid"/hard to damage*
- *GameBoy cartridges for each external device for display of data*

Hardware wish list:

- *Microprocessor with multiple interrupt levels*
- *Hardware-driven communications with GameBoy with buffer*
- *Automatic RS-232 buffer*
- *Hardware-driven communications with external devices with buffer*
- *Large amount of RAM for long-term storage of samples*

CONFIDENTI

Confidential 8/21/92

Jack –

(1/2)

The Healthdyne presentation went very well. We need to put together a complete Proposal with the following points:

1. Prototype with off the shelf components, including modem
2. Production model with custom chips and plastic
3. Software

4. Central server software – Data points to fax report conversion
5. Pilot study with 100 patients at a good medical

EXHIBIT V
PAGE 1 OF 2

Confidential

2/2

I survived the product managers picking it apart, found some great ways for them to make money with it, and the VP of marketing has bought into it.

I'd like to meet first thing monday morning to discuss it.

Steve.

PS. For now we can assume using an off the shelf meter - rather than an integrated one. After the pilot, this will be an option.

OLES, MORRISON & RINKER
LAWYERS

3300 COLUMBIA CENTER
701 FIFTH AVENUE
SEATTLE, WASHINGTON 98104-7007
(206) 623-3427
TELECOPIER: (206) 682-6234

SETH W. MORRISON
BRUCE T. RINKER
DAVID C. STEWART
SAM E. BAKER, JR.
ARTHUR D. MCGARRY
B. MICHAEL SCHESTOPOL
THEODORE L. PREG
WILLIAM G. JEFFERY
ROBERT J. BURKE
DAVID H. KARLEN

BRADLEY L. POWELL
DOUGLAS S. OLES
PETER N. RALSTON
MICHELE M. SALES
MARK F. O'DONNELL
JOHN LUKJANOWICZ
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JAMES F. NAGLE
KRIS J. SUNDBERG

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TIM W. DORE
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HARLAN M. HATFIELD
T. DANIEL HEFFERNAN
EVALYN K. HODGES
JON G. HONGLADAROM
JOHN F. JENKEL

TRAEGER MACHETANZ
GLENN R. NELSON
TODD M. NELSON
JOHN V. OHNSTAD, JR.
BRIAN E. ONORATO
J. CRAIG RUSK
ROBERT W. SARGEANT

STUART G. OLES
OF COUNSEL

GERALD DE GARMO
(1903-1988)

September 3, 1992

VIA FAX

Mr. Stephen Brown
Raya Systems, Inc.
2570 West El Camino Real, Suite 309
Mt. View, CA 94040

RE: Patent Application

Dear Steve:

As per your instructions, we have authorized Jim Anable to begin work on your application. He and his office should be contacting you frequently in the next several weeks, and it is important that you and Jack respond promptly to his questions to expedite the process.

Normally, it is optimal to do a patentability search in advance of the application to minimize the risk of denial. You have asked that the search be deferred until later so that you can meet your Sept. 23rd deadline and to avoid the extra cost. After the meeting, you might want to do a search so that you can amend the application (to the extent possible) to better avoid the prior art, and so maximize the odds of patentability. If you could afford to, it would be best to pay for the patentability search now so that it could be done while your application is being developed, and the results incorporated into the application before filing. However, because of cost considerations, I will assume you are willing to bear the risk of omitting or deferring a patentability search.

Please call if you have any questions. I will be at (509) 663-2225 from Friday until Tuesday.

Very truly yours,

OLES, MORRISON & RINKER

Richard T. Black

Richard T. Black

cc: Douglas S. Oles

OLES, MORRISON & RINKER
LAWYERS

SETH W MORRISON
BRUCE T. RINKER
DAVID C. STEWART
SAM E. BAKER, JR.
ARTHUR D. McGARRY
B. MICHAEL SCHESTOPOL
THEODORE L. PREG
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TRAEGER MACHETANZ
TODD M. NELSON
BRIAN E. ONORATO
ROBERT W. SARGEANT

September 15, 1992

James W. Anable, Esq.
Christensen, O'Connor, Johnson & Kindness
2800 Pacific First Center
1420 Fifth Avenue
Seattle, WA 98101

RE: Raya Systems, Inc.

Dear Jim:

Enclosed is Raya's check in the amount of $6,000 as a retainer for your work on Raya's patent. Please forward a receipt to Raya.

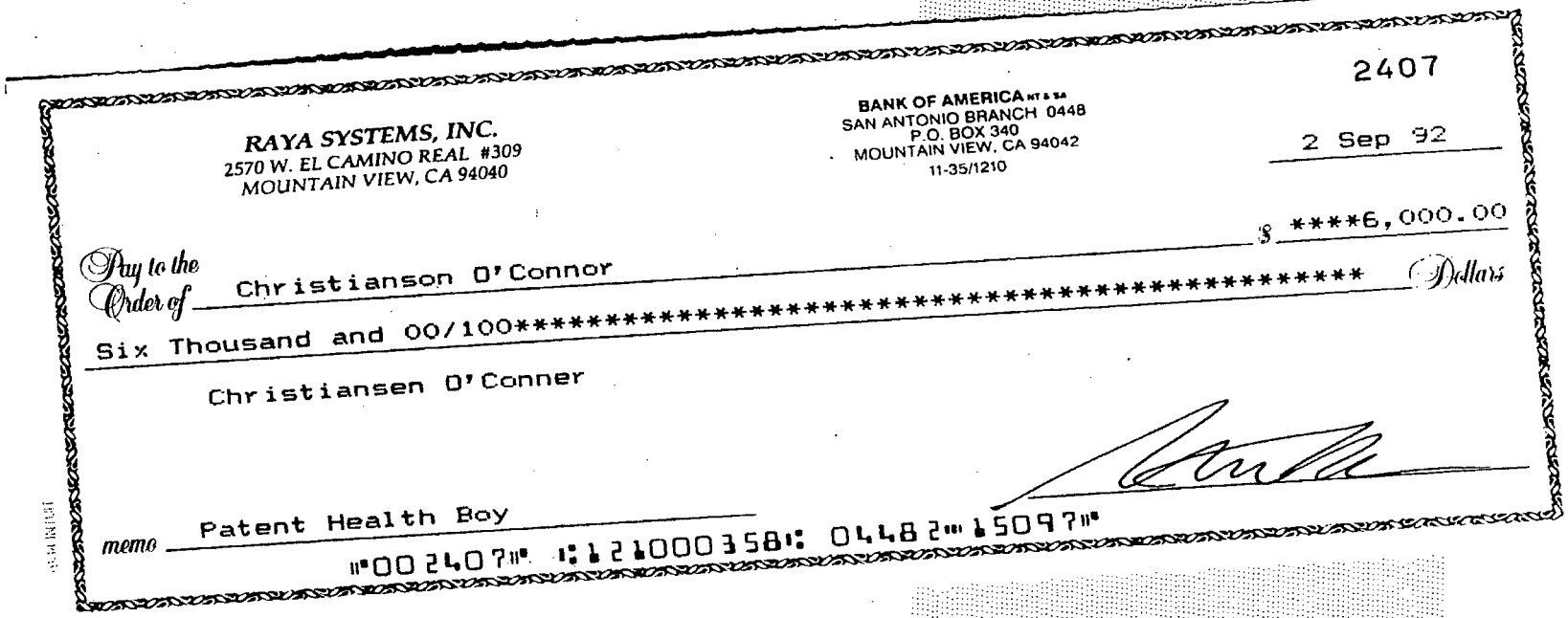
Very truly yours,

OLES, MORRISON & RINKER

Richard T. Black

Richard T. Black

RTB/jd
Enclosure
cc: Douglas Oles, Esq.



2407

RAYA SYSTEMS, INC.
2570 W. EL CAMINO REAL #309
MOUNTAIN VIEW, CA 94040

BANK OF AMERICA NT & SA
SAN ANTONIO BRANCH 0448
P.O. BOX 340
MOUNTAIN VIEW, CA 94042
11-35/1210

2 Sep 92

Pay to the Order of Christianson O'Connor $ ****6,000.00

Six Thousand and 00/100********** Dollars

Christiansen O'Conner

memo Patent Health Boy

⑈002407⑈ ⑆121000358⑆ 04482⑈15097⑈

EXHIBIT W
PAGE 3 OF 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

National Institute of Diabetes and
Digestive and Kidney Diseases
Bethesda, Maryland 20892

September 9, 1992

Our Reference: 2 R44 DK44402-02

Stephen J. Brown
President, Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040

Dear Mr. Brown:

We have begun an administrative review of the above referenced Phase II Small Business Innovation Research (SBIR) grant application in the event that it is selected for funding. As part of our administrative review, we have identified the following issues that must be addressed before any funding decision can be made.

- Human Subjects Assurance
- Confirmation of Direct and Indirect Cost Award Amounts
- Update of Other Support
- Anticipated Program Income
- Waiver of Fee/Profit

For applications involving human subjects, Public Health Service policy requires prospective grantees to submit an assurance of compliance with protection of human subjects regulations. Since the research proposed in this application involves the use of human subjects, an Assurance must be submitted to and accepted by the Office for Protection from Research Risks (OPRR), NIH. OPRR will contact you concerning the procedure for obtaining the appropriate assurance.

Current SBIR Guidelines state that the total cost (direct plus indirect) of a Phase II award may not exceed $500,000. Our preliminary review indicates that the estimated total cost is $500,000. This is based on recommended direct costs of $455,200 plus $44,800 indirect costs. Indirect costs were calculated based on a salary/wage rate of 27%.

These figures are subject to adjustment pending final indirect cost negotiation within the $500,000 limit. If an award is offered, the $500,000 will be distributed evenly for the two budget periods. Please confirm your acceptance of this in your response letter.

Please provide updated Other Support information for the Principal Investigator and all other key personnel. This information should be shown in three groups: (1) all currently active research support; (2) all applications or proposals pending review or funding; and (3) applications and proposals planned or being prepared. Include all federal and non-federal grant and contract support and specifically identify SBIR projects. For each item, give the source of funding, identifying number, project title, name of principal investigator, hours per week on the project, annual direct costs, dates of the entire period of support and a brief description of the project. If any of these overlap, duplicate, or are being replaced or supplemented by the present application, delineate and justify the nature and extent of the scientific and budgetary overlaps or boundaries.

Public Health Service (PHS) policy requires applicants for PHS research grants to include in their grant applications an estimate of the amount and source of program income expected to be generated as a result of the project for which support is being sought. The specific policies that govern the treatment of program income under research grants are set forth in the Interim Update to the 10/01/90 edition of the PHS Grants Policy Statement. Please include a statement to this effect in your response letter.

Effective with SBIR grant awards with budget period start dates of July 1, 1992, and beyond, grantee organizations may request a reasonable fee or profit as part of the total amount of the SBIR award. That is, a fee or profit may be provided <u>within</u> the maximum amount allowed under the SBIR program, which is $500,000 for Phase II grants. In your response letter, please include a statement declining or waiving this fee/profit, or a revised budget proposing inclusion of this fee/profit. Either response must be properly countersigned by your business official.

Once the above issues have been addressed satisfactorily, we will proceed with issuing a Notice of Grant Award for this project. However, please be aware that this letter does not take the place of the official award notice. Therefore, any expenditures or commitments made prior to receipt of a Notice of Grant Award, are at your own risk.

The signatures below identify the Institute staff administering this award. The Program Director should be contacted with respect to scientific and technical aspects of the award and the Grants Management Specialist should be contacted regarding business administration of the award and matters pertaining to PHS policies.

If you have any questions or if we may be of assistance, please contact us.

Sincerely,

Charles A. Wells

Charles A. Wells, Ph.D.
Diabetes Research Prog. Director
Diabetes Research Program, DPB
Div. of Diabetes, Endocrinology
and Metabolic Diseases
Room 622 Westwood (301)496-7731

Linda M. Stecklein

Linda M. Stecklein
Grants Management Officer
Grants Management Branch
Div. of Extramural Activities
Room 649 Westwood (301)496-7467

September 10, 1992

Reference: 2 R44 DK444402-02

Ms. Linda Stecklein
Grants Management Officer
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 649
Bethesda, MD 20892

Dear Ms. Stecklein:

With this letter I hope to address the questions raised in the administrative review and the budgetary concerns in the summary statement. Either Louise Novak, Patty Scheurkogel or I will follow up on each point to make sure we have provided the answers and documentation you need.

1. Budgetary Concerns in the Summary Statement. In response to the concerns in the summary statement of our Phase II Small Business Innovation Research grant, I am submitting a revised budget which addresses the issues raised. (Please find it attached to this document.)

The summary statement raised concerns that we had underestimated the amount of work to administer the proposed study. Raya Systems has grown since the original proposal, adding general administrative personnel so that researchers and project managers may more efficiently focus on their projects. Our original estimate of overhead costs did not include general office administration, and I have revised the budget to reflect our actual overhead costs. (Patty Scheurkogel, our financial manager, will provide the documentation of our 1990, 1991 and 1992 year to date overhead costs.)

In the revised budget, we have reduced the number of subjects from 250 to 200, thus requiring fewer Nintendo sets and fewer lab tests. This reduction puts an additional burden on the researchers to insure that the measures are strong enough, but I am confident we can find a way to do that. Other savings occur because the price of the Super Nintendo Entertainment System has come down to $100 from $165 at the time of the proposal.

rayasystems

Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040
phone: (415) 949-3933
fax: (415) 949-3935

The summary statement suggests that money could be saved by using computers rather that Super Nintendo Entertainment Systems. It should be noted that this proposal tests an in-the-home intervention, and the Nintendo platform was chosen not only for its appeal to children and ease of use, but also because it costs significantly less than a computer. By choosing the Nintendo system, we can supply each subject with an inexpensive, familiar, and identical platform for the experiment. We are thus able to control otherwise significant variables such as familiarity with computers and differences in computer hardware.

Since this research depends on the video game being of the same style, quality and depth as video games from the entertainment industry, we have proposed to subcontract the programming of the game based on our design to a professional Nintendo developer that works primarily for the entertainment industry. Their bid of $160,000 to program the game with the same quality and depth of other games in their portfolio such as "The Simpsons" and "Star Wars" is very reasonable, and it would cost us more to do the programming in house. Sculptured Software is able to make the bid because they can reuse tools they have developed for the entertainment industry for similar games. At Sculptured Software, there will be a project manager, programmer, artist, musician and game tester working on the project.

As indicated in the summary statement, the budgets for the consultants have been increased. After reconsidering the schedule, I have shifted some of the costs from the first year to the second year. Also, there has been a staff change for the development project manager. Jim Wehner has been replaced by Jeff George, an experienced game designer and project manager from the video game industry. (His resume is attached.)

2. Human Subjects Assurance. Louise Novak will follow up with this next week.

3. Confirmation of Direct and Indirect Cost Award Amounts. As indicated in the revised budget, the direct and indirect cost amounts are as follows:

Project Year	Direct Costs Requested	Indirect Costs Requested	Total Cost
02	216,200	33,600	249,800
03	190,900	51,000	241,900
Total	407,100	84,600	491,700

4. Update of Other Support. Two grants pending review have been funded. Patty Scheurkogel will send the updated "Other Support" pages next week.

rayasystems

Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040
phone: (415) 949-3933
fax: (415) 949-3935

5. Anticipated Program Income. We do not anticipate program income for this project until the completion of the grant support.

6. Fee/Profit. In the revised budget, the total direct and indirect costs add up to $491,700. We request a fee/profit of $8300 so that total amount remains $500,000.

I hope this letter addresses your concerns. If you have any questions, please don't hesitate to call me at (415) 949-3933. All of us at Raya Systems look forward to starting the project as soon as possible.

Sincerely,

Steve Brown
President
Raya Systems

rayasystems

Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040
phone: (415) 949-3933
fax: (415) 949-3935

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

NOTICE OF GRANT AWARD

DATE ISSUED: 09/30/92

GRANT NUMBER: ZRG1 HUD-3 (4)
2 R44 DK44402-02

TYPE OF AWARD:
AUTHORIZED BY: SMALL BUSINESS INNOVATION RESEARCH PROG
42 USC 241 42 CFR PART 52 15 USC 638

TOTAL PROJECT PERIOD:
From 09/30/92 Through 09/29/94

AWARDED BY:
NAT INST OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Title of Project or Area of Training
COMPUTER GAME FOR DIABETES EDUCATION

Grantee Organization
RAYA SYSTEMS INCORPORATED
2570 WEST EL CAMINO REAL
SUITE 309
MOUNTAIN VIEW, CA 94040

Principal Investigator/Program Director/Awardee
BROWN, STEPHEN J BS
RAYA SYSTEMS INCORPORATED
2570 WEST EL CAMINO REAL
SUITE 309
MOUNTAIN VIEW, CA 94040 12

APPROVED BUDGET

FOR BUDGET PERIOD 09/30/92 Through 09/29/93

Salaries and Wages ..... $	83,250
Fringe Benefits	
Total Personnel Costs ..... $	83,250
Consultant Costs	1,600
Equipment	58,750
Supplies	1,800
Travel - Domestic	4,000
- Foreign	
Patient Care - Inpatient	
- Outpatient	11,250
Alterations and Renovations	
Consortium/Contractual Costs	160,000
Other	200
.....	
Trainee Stipends	
Trainee Tuition and Fees	
Trainee Travel	
TOTAL DIRECT COSTS →	$ 320,850

When PHS Prior Approval is required for rebudgeting, submit requests to Grants Management Official below.

AWARD COMPUTATION

DIRECT COSTS ..... $	320,850
INDIRECT COSTS ..... $*	41,625
SBIR FEE	4,000
TOTAL ..... $	366,475
Less Unobligated Balance [Prior Period(s)] $	0
AMOUNT OF THIS AWARD → $	366,475

Base Dollars	×	Rate Percentage	=	Indirect Costs $*
83,250		50.00		41,625

SUPPORT RECOMMENDED FOR REMAINDER OF PROJECT PERIOD**

Budget Period	Total Direct Costs (Includes Stipends)
03	94,375
04	NONE

**Subject to availability of funds and satisfactory progress.

REMARKS
AMOUNT AWARDED IS THE MAXIMUM ALLOWABLE CEILING TO BE REIMBURSED UNDER THIS GRANT.

#GRANTS MANAGEMENT: MRS. LINDA M. STECKLEIN (301) 496-7467

SEE ATTACHED FOR ANY ADDITIONAL TERMS AND CONDITIONS

TERMS OF ACCEPTANCE: By acceptance of funds awarded under this grant, the grantee acknowledges that it will comply with terms and conditions in the following: (1) Legislation cited above; (2) Regulations cited above; (3) Special provisions noted above under remarks or attached to this notice; (4) PHS Grants Policy Statement; (5) 45 CFR Part 74 or 92, as applicable. The above order of precedence shall prevail.

FY—Common Accounting Number	CRS/Entity Identification No.	PHS List No./Object Class Code	Document Number
2-8425512	1770207109A1	/41.4B	(08)R4DK44402B

PROGRAM OFFICIAL
Charles A. Wells
CHARLES A. WELLS, PH.D.
DIRECTOR, DIABETES RES PROG.
DIV OF DIABETES, ENDOCRINOLOGY
AND METABOLIC DISEASES, NIDDK

PHS Grants Management Official
John R. Garthune
JOHN R. GARTHUNE
ACTING CHIEF GRANTS MGMT OFFICER
NAT INSTITUTE OF DIABETES AND
DIGESTIVE AND KIDNEY DISEASES

PHS 1533 Rev. 6/91 — Copies distributed to Principal Investigator, Program Director of Awardee, and Business Office
DUP

TERMS AND CONDITIONS

PAGE 2
2 R44 DK44402-02

- NOTICE: UNDER GOVERNING REGULATIONS, FEDERAL FUNDS ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES SHALL NOT BE EXPENDED FOR AND INDIVIDUALS SHALL NOT BE ENROLLED IN RESEARCH INVOLVING HUMAN SUBJECTS, WITHOUT PRIOR APPROVAL BY THE OFFICE FOR PROTECTION FROM RESEARCH RISKS OF AN ASSURANCE TO COMPLY WITH THE REQUIREMENTS OF 45 CFR 46 TO PROTECT HUMAN RESEARCH SUBJECTS. THIS RESTRICTION APPLIES TO ALL PERFORMANCE SITES WITHOUT OPRR-APPROVED ASSURANCES, WHETHER DOMESTIC OR FOREIGN.

- THE BUDGET PERIOD BEGIN DATE OF THIS AWARD HAS BEEN EXPEDITED. HOWEVER, BASED ON AN UNUSUAL PROVISION IN THE FY 1992 NIH APPROPRIATION THAT MANDATED A DELAY IN OBLIGATING FY 1992 FUNDS, THE BEGIN DATE FOR THIS AWARD WILL BE SEPTEMBER 30, 1992.

- AMOUNT OF THIS AWARD IS THE MAXIMUM ALLOWABLE CEILING TO BE REIMBURSED UNDER THIS GRANT SUBJECT TO ADJUSTMENT BASED ON FINAL INDIRECT COST NEGOTIATIONS AND WITHIN THE $500,000 LIMIT FOR THE -02 AND -03 BUDGET PERIODS.

- THE ESTIMATED "SUPPORT RECOMMENDED FOR REMAINDER OF PROJECT PERIOD" PLUS APPLICABLE INDIRECT COSTS ($34,850) AND FEE/PROFIT ($4,300), WHEN ADDED TO THE TOTAL AUTHORIZATION FOR THE -02 BUDGET PERIOD, MAY NOT EXCEED $500,000.

- THE TOTAL FIXED FEE FOR THE SECOND COMPETITIVE SEGMENT OF THE PROJECT IS $8,300 AND IS IN ADDITION TO ALLOWABLE DIRECT AND INDIRECT COSTS. $4,000 ARE ALLOTTED FOR PAYMENT OF FIXED FEE FOR THE BUDGET PERIOD COVERED BY THIS NOTICE OF GRANT AWARD. ADDITIONAL FUNDS FOR THE REMAINDER OF THE TOTAL FIXED FEE ARE INTENDED TO BE ALLOTTED BY THE FUTURE NOTICE OF GRANT AWARD. UNLESS AND UNTIL SUCH FUTURE NOTICE OF GRANT AWARD IS ISSUED, THE GOVERNMENT WILL NOT BE OBLIGATED TO REIMBURSE THE GRANTEE ORGANIZATION FOR MORE THAN THE FUNDS PRESENTLY ALLOTTED FOR PAYMENT OF THE FIXED FEE. AN EQUITABLE ADJUSTMENT OF THE FEE WILL BE MADE IN THE EVENT THE GRANT IS TERMINATED OR FUTURE SUPPORT IS WITHHELD. THE FEE ALLOTTED UNDER THIS NOTICE OF GRANT AWARD SHOULD BE DRAWN DOWN FROM THE DHHS PAYMENT MANAGEMENT SYSTEM IN INCREMENTS BASED UPON THE PERCENTAGE OF COMPLETION OF THE PROJECT.

- NO AMOUNT PROVIDED FOR FEE OR PROFIT MAY BE REBUDGETED INTO DIRECT OR INDIRECT COSTS OR BE REIMBURSED FOR SUCH PURPOSE(S). FURTHER, UNOBLIGATED TOTAL COSTS (EXCLUDING FEE OR PROFIT) CREATE A PROPORTIONATE UNOBLIGATED AMOUNT FOR FEE OR PROFIT.

- GENERAL PROGRAM INCOME IS TO BE TREATED UNDER THE DEDUCTION ALTERNATIVE PER 45 CFR PART 74.715.

- ALLOWABLE COSTS OF ACTIVITIES CONDUCTED BY FOR-PROFIT ORGANIZATIONS WILL BE DETERMINED BY APPLYING THE CONTRACT COST PRINCIPLES AND PROCEDURES SET FORTH IN PART 31 OF THE FEDERAL ACQUISITION REGULATIONS (FAR). HOWEVER, INDEPENDENT RESEARCH AND DEVELOPMENT COSTS (INCLUDING THE INDIRECT COSTS ALLOCABLE TO THEM) ARE UNALLOWABLE.

- TITLE TO EQUIPMENT ACQUIRED OR FABRICATED UNDER THIS GRANT SHALL VEST UPON ACQUISITION IN THE FEDERAL GOVERNMENT AND MUST BE ACCOUNTED FOR AS OUTLINED IN PART 45 OF THE FEDERAL ACQUISITION REGULATIONS (FAR). THE GRANTEE IS REQUIRED TO REPORT ALL PURCHASES OF EQUIPMENT WITH A UNIT COST OF $500 OR MORE AND HAVING A USEFUL LIFE OF MORE THAN TWO YEARS. SUCH PURCHASES SHOULD BE REPORTED IN THE ANNUAL INVENTORY (DUE OCTOBER 15TH OF EACH YEAR) ON HHS FORM 565 OR EQUIVALENT DOCUMENT TO THE PROPERTY OFFICE LISTED BELOW:

  RESEARCH CONTRACTS PROPERTY SECTION
  PERSONAL PROPERTY BRANCH
  NATIONAL INSTITUTES OF HEALTH
  BUILDING 13, ROOM 2E-65D
  BETHESDA, MD 20892
  TELEPHONE: (301) 496-6467

- PRIOR APPROVAL FROM THE AWARDING OFFICE IS REQUIRED FOR THE FOLLOWING ACTIONS:

  - CHANGE IN SCOPE OR OBJECTIVES
  - CHANGE IN PRINCIPAL INVESTIGATOR OR OTHER KEY PERSONNEL IDENTIFIED ON THE NOTICE OF GRANT AWARD.
  - ACTIVITIES OR EXPENDITURES RESTRICTED ON THE GRANT AWARD
  - CHANGE OF GRANTEE INSTITUTION/SUCCESSOR IN INTEREST/ RECIPIENT INSTITUTION NAME CHANGE
  - TRANSFERRING SUBSTANTIVE PROGRAMMATIC WORK TO A THIRD PARTY
  - CARRYOVER OF UNOBLIGATED FUNDS FROM ONE BUDGET PERIOD TO ANOTHER WITHIN AN APPROVED PROJECT PERIOD
  - EXTENSIONS OF THE BUDGET OR PROJECT PERIOD
  - PURCHASE OF EQUIPMENT COSTING MORE THAN $25,000 PER UNIT
  - ALTERATIONS AND RENOVATIONS EXCEEDING $25,000 IN A BUDGET PERIOD
  - PATIENT CARE COSTS WHERE THE NEED HAS NOT PREVIOUSLY BEEN APPROVED BY PHS AND/OR WHEN THE GRANTEE DESIRES TO REBUDGET FUNDS OUT OF THE PATIENT CARE CATEGORY
  - PREAWARD COSTS INCURRED MORE THAN 90 DAYS PRIOR TO THE EFFECTIVE DATE OF ANY NEW OR COMPETING CONTINUATION AWARD

- TRANSFERRING MANAGEMENT SERVICES TO A THIRD PARTY WHICH EXCEED $25,000
- CONSULTANT FEES WHEN ARRANGEMENT CONSTITUTES TRANSFER OF SUBSTANTIVE PROGRAMMATIC WORK TO A THIRD PARTY
- RETROACTIVE PRIOR APPROVAL

SUCH PRIOR APPROVAL SHOULD BE REQUESTED IN A LETTER SIGNED BY THE PRINCIPAL INVESTIGATOR AND A BUSINESS OFFICIAL OF THE GRANTEE INSTITUTION, SHOULD BE ADDRESSED TO THE GRANTS MANAGEMENT CONTACT IDENTIFIED ON THE NOTICE OF GRANT AWARD, AND SHOULD INCLUDE AN EXPLANATION AND JUSTIFICATION FOR THE ACTION(S). THE ABOVE IS AN ABBREVIATED LIST AND DOES NOT INCLUDE ALL ACTIONS WHICH REQUIRE PRIOR APPROVAL. IF THERE ARE ANY QUESTIONS AS TO WHETHER AN ACTION REQUIRES PRIOR APPROVAL OR NOT, CONTACT THE GRANTS MANAGEMENT REPRESENTATIVE.

O'CONNOR JOHNSON KINDNESS

PATENT, TRADEMARK AND OTHER INTELLECTUAL PROPERTY MATTERS

FAX: (206) 224-0779
TELEX: 4938023
CABLE: PATENTABLE

FACSIMILE COVER SHEET

DATE: October 2, 1992

TO: Steve Brown/Jack Thornton

Raya Systems, Inc.

FACSIMILE NUMBER: (415) 949-3935

RE: Patent Application

OUR REFERENCE: RAYA-1-6631

YOUR REFERENCE:

FROM: James W. Anable, Esq.

(Facsimile No. (206) 224-0779 - Panafax Groups 1, 2 & 3)

MESSAGE:

Please review and contact me. I am out of the office this morning but expect to return by noon. I will await your call.

Enclosures: Patent Application (DRAFT) and drawings (DRAFT)

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MODULAR MICROPROCESSOR-BASED HEALTH MONITORING SYSTEM

Field of the Invention

This invention relates to administering and monitoring personal healthcare. More specifically, this invention relates to self-care health monitoring arrangements that enable a patient or other user to gather data important to a health management program and, if desired or necessary, easily provide that data to a healthcare professional.

Background of the Invention

Controlling or curing conditions of ill health generally involves both establishing a therapeutic program and monitoring the progress of the afflicted person. Based on that progress, decisions can be made as to altering therapy to achieve a cure or maintain the affliction or condition at a controlled level. Successfully treating certain health conditions calls for rather frequent monitoring and a relatively high degree of patient participation. For example, in order to establish and maintain a regimen for successful diabetes care, a diabetic should monitor his or her blood glucose level and record that information along with the date and time at which the monitoring took place. Since diet, exercise, and medication all affect blood glucose levels, a diabetic often must record data relating to those items of information along with blood glucose level so that the diabetic may more closely monitor his or her condition and, in addition, can provide information of value to

the healthcare provider in determining both progress of the patient and detecting any need to change the patient's therapy program.

Advances in the field of electronics over the past several years have brought about significant changes in medical diagnostic and monitoring equipment, including arrangements for self-care. With respect to the control and monitoring of diabetes, relatively inexpensive and relatively easy-to-use blood glucose monitoring systems have become available that provide reliable information that allows a diabetic and his or her healthcare professional to establish, monitor and adjust a treatment plan (diet, exercise, and medication). More specifically, microprocessor-based blood glucose monitoring systems are being marketed which sense the glucose level of a blood sample that is applied to a reagent-impregnated region of a test strip that is inserted in the glucose monitor. When the monitoring sequence is complete, the blood glucose level is displayed by, for example, a liquid crystal display (LCD) unit.

Typically, currently available self-care blood glucose monitoring units include a calendar/clock circuit and a memory circuit that allows a number of blood glucose test results to be stored along with the date and time at which the monitoring occurred. The stored test results (blood glucose level and associated time and date) can be sequentially recalled for review by the blood glucose monitor user or a health professional by sequentially actuating a push button or other control provided on the monitor. In some commercially available devices, the average of the blood glucose results that are stored in the monitor (or the average of the results for a predetermined period of time, e.g., fourteen days) also is displayed during the recall sequence. Further, some self-care blood glucose monitors allow the user to tag the test result with an "event code" that can be used to organize the test results into categories. For example, a user might use a specific event code to identify test results obtained at a particular times of the day, a different

event code to identify a blood glucose reading obtained after a period of exercise, two additional event codes to identify blood glucose readings taken during hypoglycemia symptoms and hyperglycemia symptoms, etc. When event codes are provided and used, the event code typically is displayed with each recalled blood glucose test result.

Microprocessor-based blood glucose monitoring systems have advantages other than the capability of obtaining reliable blood glucose test results and storing a number of the results for later recall and review. By using low power microprocessor and memory circuits and powering the units with small, high capacity batteries (e.g., a single alkaline battery), extremely compact and light designs have been achieved that allow taking the blood glucose monitoring system to work, school, or anywhere else the user might go with people encountered by the user not becoming aware of the monitoring system. In addition, most microprocessor-based self-care blood glucose monitoring systems have a memory capacity that allows the system to be programmed by the manufacturer so that the monitor displays a sequence of instructions during any necessary calibration or system tests and during the blood glucose test sequence itself. In addition, the system monitors various system conditions during a blood glucose test (e.g., whether a test strip is properly inserted in the monitor and whether a sufficient amount of blood has been applied to the reagent impregnated portion of the strip) and if an error is detected generates an appropriate display (e.g., "retest"). A data port may be provided that allows test results stored in the memory of the microprocessor-based blood glucose monitoring system to be transferred to a data port (e.g., RS-232 connection) of a personal computer or other such device for subsequent analysis.

Microprocessor-based blood glucose monitoring systems are a significant advance over previously available self-care systems such as those requiring a diabetic to apply a blood sample to reagent activated portions of a test strip; wipe the blood sample from the

test strip after a predetermined period of time; and, after a second predetermined period of time, determine blood glucose level by comparing the color of the reagent activated regions of the test strip with a color chart supplied by the test strip manufacturer. However, several drawbacks and disadvantages exist, thus leaving several areas in which improvements would be of benefit both to the user and the healthcare professional. For example, establishing and maintaining diabetic healthcare often requires the diabetic to record additional data pertaining to medication, food intake, and exercise. However, the event codes of currently available microprocessor blood glucose monitoring systems do not allow the user of the system to tag and track blood glucose test results on a sufficiently accurate quantitative basis. For example, it would only be possible for the user to use the available event codes to classify stored blood glucose readings to indicate blood glucose tests taken immediately after a heavy meal and to identify blood glucose test results obtained after normal and light meals. This method of recording information not only requires subjective judgment by the system user, but will not suffice in a situation in which successfully controlling the user's diabetes requires the recording and tracking of relatively accurate information relating to food intake, exercise, or medication (e.g., insulin dosage). An otherwise significant advantage of currently available blood glucose monitoring systems is lost when blood glucose test results must be recorded and tracked with quantitative information relating to medication, food intake, or exercise. Specifically, the system user must record the required information along with a time and date tagged blood glucose test result by, for example, writing the information in a log book.

The use of event codes to establish subcategories of blood glucose test results has an additional disadvantage or drawback. In particular, although alphanumeric display devices are typically used in currently available microprocessor-based blood glucose

monitoring systems, the display units are limited to a single line of information having on the order of six characters. Moreover, since the systems include no provision for the user to enter alphanumeric information, any event codes that are used must be indicated on the display in a generic manner, e.g., displayed as "EVENT 1", "EVENT 2", etc. This limitation makes the system more difficult to use because the diabetic must either memorize his or her assignment of event codes or maintain a list that defines the event codes. The limited amount of data that can be displayed at any one time presents additional drawbacks and disadvantages. First, instructions and diagnostics that are displayed to the user when calibrating the system and using the system to obtain a blood glucose reading must be displayed a line at a time and in many cases, the information must be displayed in a cryptic manner. This limitation increases the likelihood that some potential users of the system (particularly children and the elderly) either will find the system complex to use or will not achieve the maximum benefit available from system use.

The above-discussed display limitations and other aspects of currently available blood glucose monitoring systems is disadvantageous in yet another way. Little statistical information can be made available to the user. For example, in diabetic healthcare maintenance, changes or fluctuations that occur in blood glucose levels during a day, a week, or longer period can provide valuable information to a diabetic and/or his or her healthcare professional. As previously mentioned, currently available systems do not allow associating blood glucose test results with attendant quantitative information relating to medication, food intake, or other factors such as exercise that affect a person's blood glucose level at any particular point in time. Thus, currently available blood glucose monitoring systems are not able to generate or display trend information that may be of significant value to a diabetic or the diabetic's healthcare professional.

The lack of provision for the entering of alphanumeric data also can be a disadvantage. For example, currently available blood glucose monitoring systems do not allow the user or the healthcare professional to enter information into the system such as medication dosage and other instructions or data that is relevant to the user's self-care health program.

The above-discussed disadvantages and drawbacks of currently available microprocessor-based blood glucose monitoring systems also have been impediments to adopting the basic technology of the system for other healthcare situations in which establishing and maintaining an effective regimen for cure or control is dependent upon (or at least facilitated by) periodically monitoring a condition and recording that condition along with time and date tags and other information necessary or helpful in establishing and maintaining a healthcare program.

Summary of the Invention

This invention provides a new and useful system for healthcare maintenance in which the invention serves as a peripheral device to a small handheld microprocessor-based unit of the type that includes a display screen, buttons or keys that allow a user to control the operation of the device and a program cartridge or other arrangement that can be inserted in the device to adapt the device to a particular application or function. The invention in effect converts the handheld microprocessor device into a healthcare monitoring system that has significant advantages over systems such as the currently available blood glucose monitoring systems. To perform this conversion, the invention includes a microprocessor-based healthcare data management unit, a program cartridge and a monitoring unit. When inserted in the handheld microprocessor unit, the program cartridge provides the software necessary to program the handheld microprocessor unit for operation with the microprocessor-based data management unit. Signal

communication between the data management unit and the handheld microprocessor unit is established by an interface cable. A second interface cable can be used to establish signal communication between the data management unit and the monitoring unit or, alternatively, the monitoring unit can be constructed as a plug-in unit having an electrical connector that mates with a connector mounted within a region that is configured for receiving the monitoring unit.

In operation, the control buttons or keys of the handheld microprocessor-based unit are used to select the operating mode for both the data management unit and the handheld microprocessor-based unit. In response to signals generated by the control buttons or keys, the data management unit generates signals that are coupled to the handheld microprocessor unit and, under control of the software contained in the program cartridge, establish an appropriate screen display on the handheld microprocessor-based unit display. In selecting system operating mode and other operations, the control buttons are used to position a cursor or other indicator in a manner that allows the system user to easily select a desired operating mode or function and provide any other required operator input. In the disclosed detailed embodiment of the invention several modes of operation are made available.

Brief Description of the Drawings

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1 is a block diagram that illustrates a healthcare monitoring system arranged in accordance with the invention;

FIGURE 2 diagrammatically illustrates monitoring systems constructed in accordance with the invention connected in signal communication with a remotely located computing facility which includes provision for making the data supplied by the monitoring system of the invention available to a designated healthcare professional and/or for providing data and instructions to the system user;

FIGURE 3 is a block diagram diagrammatically depicting the structural arrangement of the system data management unit and its interconnection with other components of the system shown in FIGURE 1; and

FIGURES 4-10 depict typical system screen displays of data and information that can be provided by the arrangements shown in FIGURES 1-3.

Detailed Description

FIGURE 1 depicts a self-care health monitoring system arranged in accordance with the invention. In the arrangement shown in FIGURE 1, a data management unit 10 is electrically interconnected with a handheld microprocessor-based unit 12 via a cable 14. Data management unit 10 also is electrically interconnected with a blood glucose monitor 16 of the type capable of sensing blood glucose level and producing an electrical signal representative thereof. Although FIGURE 1 illustrates blood glucose monitor 16 as being connected to data management unit 10 by a cable 18, it may be preferable to construct blood glucose monitor 16 as a plug-in unit that is placed in a recess or other suitable opening or slot in data management unit 10. Regardless of the manner in which blood glucose monitor 16 is interconnected with data management unit 10, both that interconnection and cable 14 are configured for serial data communication between the interconnected devices.

Also shown in FIGURE 1 are two additional monitoring devices 20 and 22, which are electrically connected for serial data communication with data management unit 10

via cables 24 and 26, respectively. Monitoring units 20 and 22 of FIGURE 1 represent devices other than blood glucose monitor 16 that can be used in the practice of the invention. For example, monitors can be provided for monitoring conditions such as blood pressure, pulse, and body temperature to thereby realize systems for self-care monitoring and control of conditions such as hypertension, certain heart conditions and various other afflictions and physical conditions. As is the case with blood glucose monitor 16, the additional monitors can be configured as plug-in units that are directly received by data management unit 10, or can be connected to data management unit 10 with cables (as shown in FIGURE 1).

As is shown in FIGURE 1, handheld microprocessor unit 12 includes a display screen 28 and a plurality of switches or keys (30, 32, 34, 36, and 38 in FIGURE 1), which are mounted on a small housing 40. Located in the interior of housing 40, but not shown in FIGURE 1, are a microprocessor, memory circuits, and circuitry that interfaces switches 30, 32, 34, 36 and 38 with the microprocessor. Stored in the memory of program handheld microprocessor unit 12 is a set of program instructions that establishes a data protocol that allows handheld microprocessor unit 12 to perform digital data signal processing and generate desired data or graphics for display on display unit 28 when a program cartridge 42 is inserted in a slot or other receptacle in housing 40. That is, program cartridge 42 includes read-only memory units (or other memory means such as battery-powered random access memory) which stores program instructions and data. When combined with program instructions and data included in the internal memory circuits of handheld microprocessor unit 12, the instructions and data of program cartridge 42 cause handheld microprocessor unit 12 to be programmed for a particular purpose or use. As is known in the art, the program instructions and data stored in the internal memory of handheld microprocessor-based unit 12 can be configured and

arranged so that different program cartridges configure handheld microprocessor unit 12 for different applications or purposes. In each such purpose or application, the plurality of switches or keys (30, 32, 34, 36, and 38 in FIGURE 1) are selectively operated to provide signals that result in pictorial and/or printed information being displayed by display unit 42.

Various devices are known that meet the above-set forth description of handheld microprocessor unit 12. For example, compact devices are available in which the plurality of keys allows alphanumeric entry and internal memory is provided for storing information such as names, addresses, phone numbers, and an appointment calendar. Small program cartridges or cards can be inserted in these devices to program the device for various purposes such as the playing of games, spreadsheet application, and foreign language translation sufficient for use in travel. More recently, less compact products that have more extensive computational capability and are generally called "palm top computers" have been introduced into the marketplace. These devices also can include provision for programming the device by means of an insertable program card or cartridge.

The currently preferred embodiments of the invention are configured and arranged to operate in conjunction with yet another type of handheld microprocessor unit. Specifically, in the currently preferred embodiments of the invention, program cartridge 42 is electrically and physically compatible with commercially available compact video game systems, such as the system manufactured by Nintendo of America Inc. under the trademark "GAME BOY." Configuring data management unit 10 and program cartridge 42 for operation with a handheld video game system has several advantages. For example, the display unit of such a device provides display resolution that allows the invention to display both multi-line alphanumeric information and graphical data. In this

regard, the 160 x 144 pixel dot matrix-type liquid crystal display screen currently used in the above-referenced compact video game systems provides sufficient resolution for at least six lines of alphanumeric text, as well as allowing graphical representation of statistical data such as graphical representation of blood glucose test results for a day, a week, or longer.

Another advantage of realizing handheld microprocessor unit 12 in the form of a compact video game system is the relatively simple, yet versatile arrangement of switches that is provided by such a device. For example, as is indicated in FIGURE 1, a compact video game system includes a control pad 30 that allows an object displayed on display unit 42 to be moved in a selected direction (i.e., up-down or left-right). As also is indicated in FIGURE 1, compact video game systems typically provide two pair of distinctly-shaped push button switches. In the arrangement shown in FIGURE 1, a pair of spaced-apart circular push button switches (36 and 38) and a pair of elongate switches (32 and 34) are provided. The functions performed by the two pairs of switches is dependent upon the program instructions contained in each program cartridge 42.

Yet another advantage of utilizing a compact video game system for handheld microprocessor based unit 12 of FIGURE 1 is the widespread popularity and low cost of such units. In this regard, manufacture and sale of a data management unit 10, blood glucose monitor 16 and program cartridge 42 that operate in conjunction with a compact microprocessor based video allows the self-care health monitoring system of FIGURE 1 to be manufactured and sold at a lower cost than could be realized in an arrangement in which handheld unit 12 is designed and manufactured solely for use in the system of FIGURE 1.

An even further advantage of using a compact video game system for handheld microprocessor 12 is that such video game systems include means for easily establishing

the electrical interconnection provided by cable 14 in FIGURE 1. In particular, such compact video game systems include a connector mounted to the game unit housing (40 in FIGURE 1) and a cable that can be connected between the connectors of two video game units to allow interactive operation of the two interconnected units (i.e., to allow contemporaneous game play by two players or competition between players as they individually play identical but separate games). In the preferred embodiments of the invention, the "two-player" cable supplied with the compact video game unit being used as handheld microprocessor unit 12 is used as cable 14 to establish serial data communication between the handheld microprocessor unit 12 (compact video game system) and data management unit 10. In these preferred embodiments, the program instructions stored on the memory of data management unit 10 and program cartridge 42 respectively program data management unit 10 and the compact video game system (i.e., handheld microprocessor unit 12) for interactive operation in which switches 30, 32, 34, 36 and 38 are used to control the operation of data management unit 10 (e.g., to select a particular operational mode such as performance of a blood glucose test or the display of statistical test data and, in addition, to control operation such as selection of an option during operation of the system in a particular operational mode). In each operational mode, data management unit 10 processes data in accordance with program instructions stored in the memory circuits of data management unit 10. Depending upon the operational mode selected by the user, data is supplied to data management unit 10 by blood glucose monitor 16, by additional monitors (20 and 22 in FIGURE 1) or any interconnected computers (hereinafter described as elements 48 and 54 in FIGURE 1) During operational mode, switches 30, 32, 34, 36 and 38 are selectively activated so that signals are selectively coupled to the video game system (handheld microprocessor unit 12) and processed in accordance with program instructions stored in program

cartridge 42. The signal processing performed by handheld microprocessor unit 12 results in the display of alphanumeric, symbolic, or graphic information on the video game display screen (i.e., display unit 28 in FIGURE 1) which allow the user to control system operation and obtain desired test results and other information.

With continued reference to FIGURE 1, data management unit 10 of the currently preferred embodiments of the invention includes a data port 44 that allows communication between data management unit 10 and a personal computer 48 (or other programmable data processor). In the currently preferred embodiments of the invention, data port 44 is an RS-232 connection that allows serial data communication between data management unit 10 and personal computer 48. In the practice of the invention, personal computer 48 can be used to supplement data management unit 10 by, for example, performing relatively complex or sophisticated analyses of blood glucose and other data that has been supplied to and stored in the memory circuits of data management unit 10. Alternatively, personal computer 48 can be used to supply data to data management unit 10 that is not conveniently supplied by using handheld microprocessor switches 30, 32, 34, 36 and 38 as an operator interface to the system shown in FIGURE 1. For example, some embodiments of the invention may employ a substantial amount of alphanumeric information that must be entered by the system user. Although it is possible to enter such data by using switches 30, 32, 34, 36 and 38 in conjunction with menus and selection screens displayed on display screen 28 of FIGURE 1, it may be more advantageous to use a device such as personal computer 48 for entry of such data. However, if personal computer 48 is used in this manner, some trade-off of system features may be required because data management unit 10 must be temporarily interconnected with personal computer 48 during these operations. That is, some loss of

system mobility might result because a suitably programmed personal computer would be needed at each location at which data entry or analysis is to occur.

As is indicated in FIGURE 1, data management unit 10 of the currently preferred embodiments of the invention also includes a modem that allows data communication between data management unit 10 and a remote computing facility 54 via a conventional telephone line (indicated by reference numeral 50 in FIGURE 1) and a modem 52 that interconnects remote computing facility 54 and telephone line 50. As shall be described in more detail, remote computing facility 54 facilitates communication between a user of the system shown in FIGURE 1 and his or her healthcare professional and can provide additional services such as updating system software.

Regardless of whether a compact video game system, another type of commercially available handheld microprocessor-based unit, or a specially designed unit is used, the preferred embodiments of FIGURE 1 provide a self-care blood glucose monitoring system in which program cartridge 42: (a) adapts handheld microprocessor unit 12 for displaying instructions for performing the blood glucose test sequence and associated calibration and test procedures; (b) adapts handheld microprocessor unit 12 for displaying (graphically or alphanumerically) statistical data such as blood glucose test results taken during a specific period of time (e.g., a day, week, etc.); (c) adapts handheld microprocessor unit 12 for supplying control signals and signals representative of food intake or other useful information to data management unit 10; (d) adapts handheld microprocessor unit 12 for simultaneous graphical display of blood glucose levels with information such as food intake; and, (e) adapts handheld microprocessor unit 12 for displaying information or instructions from a healthcare professional that are coupled to data management unit 10 from a remote computing facility 54. The manner in which the

arrangement of FIGURE 1 implements the above-mentioned functions and others can be better understood with reference to FIGURES 2 and 3.

Referring first to FIGURE 2, in relatively large scale application of the invention, remote computing facility 54 of FIGURE 1 functions as a clearinghouse (i.e., central server) that is identified by reference numeral 56 in FIGURE 2. Clearinghouse 56 receives data from a plurality of self-care microprocessor-based healthcare systems of the type shown in FIGURE 1, with the individual self-care health monitoring systems being indicated in FIGURE 2 by reference numeral 58. Preferably, the data supplied to clearinghouse 56 by each individual self-care health monitoring system 58 consists of "raw data," i.e., test results and related data that was stored in memory circuits of data management unit 10, without further processing by data management unit 10. For example, with respect to the arrangement shown in FIGURE 1, blood glucose test results and associated data such as food intake information, medication dosage and other such conditions are transmitted to clearinghouse 56 and stored with a digitally encoded signal that identifies both the source of the information (i.e., the system user or patient) and those having access to the stored information (i.e., the system user's doctor or other healthcare professional).

In FIGURE 2, rectangular outline 60 represents one of numerous remotely located healthcare professionals who can utilize clearinghouse 56 and the arrangement described relative to FIGURE 1 in monitoring and controlling patient healthcare programs. Shown within outline 60 is a computer 62 (e.g., personal computer), which is coupled to clearinghouse 56 by means of a modem (not shown in FIGURE 2) and a telephone line 64. The arrangement of FIGURE 2 also diagrammatically indicates a facsimile machine ("fax"), which is coupled to clearinghouse 56 by means of a second

device such as a mouse), the healthcare professional can establish data communication between computer 62 and clearinghouse 56 via telephone line 64. Once data communication is established between computer 62 and clearinghouse 56, patient information can be obtained from clearinghouse 56 in a manner similar to the manner in which subscribers to various database services access and obtain information. In particular, the healthcare professional can transmit an authorization code to clearinghouse 56 that identifies the healthcare professional as an authorized user of the clearinghouse and, in addition, can transmit a signal representing the patient for which healthcare information is being sought. As is the case with conventional database services and other arrangements, the identifying data is keyed into computer 62 by means of a conventional keyboard (not shown in FIGURE 2) in response to prompts that are generated at clearinghouse 56 for display by the display unit of computer 62 (not shown in FIGURE 2).

Depending upon the hardware and software arrangement of clearinghouse 56 and selections made by the healthcare professional via computer 62, patient information can be provided to the healthcare professional in different ways. For example, computer 62 can be operated to access data in the form that it is stored in the memory circuits of clearinghouse 56 (i.e., raw data that has not been processed or altered by the computational or data processing arrangements of clearinghouse 56). Such data can be processed, analyzed, printed and/or displayed by computer 62 using commercially available or custom software. On the other hand, various types of analyses may be performed by clearinghouse 56 with the results of the analyses being transmitted to the remotely located healthcare professional 60. For example, clearinghouse 56 can process and analyze data in a manner identical to the processing and analysis provided by the self-care monitoring system of FIGURE 1. With respect to such processing and any other

analysis and processing provided by clearinghouse 56, results expressed in alphanumeric format can be sent to computer 62 via telephone line 64 and the modem associated with computer 62, with conventional techniques being used for displaying and/or printing the alphanumeric material for subsequent reference. In addition, the arrangement of FIGURE 2 allows analytical or statistical results to be transmitted to remotely located healthcare professional 60 via telephone line 68 and facsimile machine 66. For example, data supplied by the arrangement can be processed by clearinghouse 56 using conventional data processing techniques to obtain a collection of data or statistical information that lends itself to presentation in a pictorial or graphic format. In such a case, the data can be converted by clearinghouse 56 to a conventional facsimile transmission format, which can be sent to the healthcare professional's facsimile machine 66 upon request of the healthcare professional (i.e., communication via computer 62).

The arrangement of FIGURE 2 also allows the healthcare professional to send messages and/or instructions to each patient via computer 62, telephone line 64, and clearinghouse 56. In particular, clearinghouse 56 can be programmed to generate a menu that is displayed by computer 62 and allows the healthcare professional to select a mode of operation in which information is to be sent to clearinghouse 56 for subsequent transmission to a user of the system described relative to FIGURE 1. This same menu (or related submenus) can be used by the healthcare professional to select one or more modes of operation of the above-described type in which either unmodified patient data or the results of data that has been analyzed by clearinghouse 56 is provided to the healthcare provider via computer 62 and/or facsimile machine 66.

In the currently contemplated arrangements, operation of the arrangement of FIGURE 2 to provide the user of the invention with messages or instructions such as

changes in medication or other aspects of the healthcare program is similar to the operation that allows the healthcare professional to access data sent by a patient, i.e., transmitted to clearinghouse 56 by a data management unit 10 of FIGURE 1. The process differs in that the healthcare professional enters the desired message or instruction via the keyboard or other interface unit of computer 62. Once the data is entered and transmitted to clearinghouse 56, it is stored for subsequent transmission to the user for whom the information or instruction is intended.

With respect to transmitting stored messages or instructions to a user of the invention, at least two techniques are available. The first technique is based upon the manner in which operational modes are selected in the practice of the invention. Specifically, in the currently preferred embodiments of the invention, program instructions that are stored in data management unit 10 and program cartridge 42 cause the system of FIGURE 1 to generate menu screens which are displayed by display unit 28 of handheld microprocessor unit 12. The menu screens allow the system user to select the basic mode in which the system of FIGURE 1 is to operate and, in addition, allow the user to select operational subcategories within the selected mode of operation. Various techniques are known to those skilled in the art for displaying and selecting menu items. For example, in the practice of this invention, one or more main menus can be generated and displayed which allow the system user to select operational modes that may include: (a) a monitor mode (e.g., monitoring of blood glucose level); (b) a display mode (e.g., displaying previously obtained blood glucose test results or other relevant information); (c) an input mode (e.g., a mode for entering data such as providing information that relates to the healthcare regimen, medication dosage, food intake, etc., and (d) a communications mode (for establishing a communication link between data management

unit 10 and personal computer 48 of FIGURE 1; or between data management Unit 10 and a remote computing facility such as clearinghouse 56 of FIGURE 2).

In embodiments of the invention that employ a compact video game system for handheld microprocessor unit 12, the selection of menu screens and the selection of menu screen items preferably is accomplished in substantially the same manner as menu screens and menu items are selected during the playing of a video game. For example, the program instructions stored in data management unit 10 and program cartridge 42 of the arrangement of FIGURE 1 can be established so that a predetermined one of the compact video game switches (e.g., switch 32 in FIGURE 1) allows the system user to select a desired main menu in the event that multiple main menus are employed. When the desired main menu is displayed, operation by the user of control pad 30 allows a cursor or other indicator that is displayed on the menu to be positioned adjacent to or over the menu item to be selected. Activation of a switch (e.g., switch 36 of the depicted handheld microprocessor unit 12) causes the handheld microprocessor unit 12 and/or data management unit 10 to initiate the selected operational mode or, if selection of operational submodes is required, causes handheld microprocessor unit 12 to display a submenu.

In view of the above-described manner in which menus and submenus are selected and displayed, it can be recognized that the arrangement of FIGURE 1 can be configured and arranged to display a menu or submenu item that allows the user to obtain and display messages or instructions that have been provided by a healthcare professional and stored in clearinghouse 56. For example, a submenu that is generated upon selection of the previously mentioned communications mode can include submenu items that allow the user to select various communication modes, including a mode in which serial data communication is established between data management unit 10 and clearinghouse 56 and

data management unit 10 transmits a message status request to clearinghouse 56. When this technique is used, the data processing system of clearinghouse 56 is programmed to search the clearinghouse memory to determine whether a message exists for the user making the request. Any messages stored in memory for that user are then transmitted to the user and processed for display on display unit 28 of handheld microprocessor unit 12. If no messages exist, clearinghouse 56 transmits a signal that causes display unit 28 to indicate "no messages." In this arrangement, clearinghouse 56 preferably is programmed to store a signal indicating that a stored message has been transmitted to the intended recipient (user). Storing such a signal allows the healthcare professional to determine that messages sent to clearinghouse 56 for forwarding to a patient have been transmitted to that patient. In addition, the program instructions stored in data management unit 10 of FIGURE 1 preferably allow the system user to designate whether received messages and instructions are to be stored in the memory of data management unit 10 for subsequent retrieval or review. In addition, in some instances it may be desirable to program clearinghouse 56 and data management unit 10 so that the healthcare professional can designate (i.e., flag) information such as changes in medication that will be prominently displayed to the user (e.g., accompanied by a blinking indicator) and stored in the memory of data management unit 10 regardless of whether the system user designates the information for storage.

A second technique that can be used for forwarding messages or instructions to a user does not require the system user to select a menu item requesting transmission by clearinghouse 56 of messages that have been stored for forwarding to that user. In particular, clearinghouse 56 can be programmed to operate in a manner that either automatically transmits stored messages for that user when the user operates the system of FIGURE 1 to send information to the clearinghouse or programmed to operate in a

manner that informs the user that messages are available and allows the user to access the messages when he or she chooses to do so.

FIGURE 3 illustrates the manner in which data management unit 10 is arranged and interconnected with other system components for effecting the above-described operational aspects of the invention and additional aspects that are described relative to FIGURES 4-10. As is symbolically indicated in FIGURE 3, handheld microprocessor unit 12 and blood glucose monitor 16 are connected to a dual universal asynchronous receiver transmitter 70 (e.g., by cables 14 and 18 of FIGURE 1, respectively). As also is indicated in FIGURE 3 when a personal computer 48 (or other programmable digital signal processor) is connected to data port 44 signal communication is established between personal computer 48 and a second dual universal asynchronous receiver transmitter 72, which is included in data management unit 10. Additionally, dual universal asynchronous receiver transmitter 72 is coupled to modem 46 so that data communication can be established between data management unit 10 and a remote computing facility 54 (e.g., clearinghouse 56 of FIGURE 2).

Currently preferred embodiments of data management unit 10 include a plurality of signal sensors 74, with an individual signal sensor being associated with each device that is (or may be) interconnected with data management unit 10. As previously discussed and as is indicated in FIGURE 3, these devices include handheld microprocessor unit 12, blood glucose monitor 16, personal computer 48, and remote computing facility 54. Each signal sensor 74 that is included in data management unit 10 is electrically connected for receiving a signal that will be present when the device with which that particular signal sensor is associated is connected to data management unit 10 and, in addition, is energized (e.g., turned on). For example, in previously mentioned embodiments of the invention in which data port 44 is an RS-232 connection, the signal

sensor 74 that is associated with personal computer 48 can be connected to an RS-232 terminal that is supplied power when a personal computer is connected to data port 44 and the personal computer is turned on. In a similar manner, the signal sensor 74 that is associated with remote computing facility 54 can be connected to modem 46 so that the signal sensor 74 receives an electrical signal when modem 46 is interconnected to a remote computing facility (e.g., clearinghouse 56 of FIGURE 2) via a telephone line 50.

In the arrangement of FIGURE 3, each signal sensor 74 is a low power switch circuit (e.g., a metal-oxide semiconductor field-effect transistor circuit), which automatically energizes data management unit 10 whenever one or more of the devices associated with signal sensors 74 are connected to data management unit 10 and are energized. Thus, as is indicated in FIGURE 3 by signal path 76, each signal sensor 74 is interconnected with power supply 78, which supplies operating current to the circuitry of data management unit 10 and typically consists of one or more small batteries (e.g., three AAA alkaline cells).

The microprocessor and other conventional circuitry that enables data management unit 10 to process system signals in accordance with stored program instructions is indicated in FIGURE 3 by central processing unit (CPU) 80. As is indicated in FIGURE 3 by interconnection 82 between CPU 80 and battery 78, CPU 80 receives operating current from power supply 78, with power being provided only when one or more of the signal sensors 74 are activated in the previously described manner. A clock/calendar circuit 84 is connected to CPU 80 (via signal path 86 in FIGURE 3) to allow time and date tagging of blood glucose tests and other information. Although not specifically shown in FIGURE 3, operating power is supplied to clock/calendar 84 at all times.

In operation, CPU 80 receives and sends signals via a data bus (indicated by signal path 88 in FIGURE 3) which interconnects CPU 80 with dual universal asynchronous receiver transmitters 70 and 72. The data bus 88 also interconnects CPU 80 with memory circuits which, in the depicted embodiment, include a system read-only memory (ROM) 90, a program random access memory (RAM) 92, and an electronically erasable read-only memory (EEROM) 94. System ROM 90 stores program instructions and any data required in order to program data management unit 10 so that data management unit 10 and a handheld microprocessor unit 12 that is programmed with a suitable program cartridge 72 provide the previously discussed system operation and system operation that will be described relative to FIGURES 4-10. During operation of the system, program RAM 92 provides memory space that allows CPU 80 to carry out various operations that are required for sequencing and controlling the operation of the system of FIGURE 1. In addition, RAM 92 can provide memory space that allows external programs (e.g., programs provided by clearinghouse 56) to be stored and executed. EEROM 94 allows blood glucose test results and other data information to be stored and preserved until the information is no longer needed (i.e., until purposely erased by operating the system to provide an appropriate erase signal to EEROM 94).

FIGURES 4-10 illustrate typical screen displays that are generated by the arrangement of the invention described relative to FIGURES 1-3. Reference will first be made to FIGURES 4 and 5, which exemplify screen displays that are associated with operation of the invention in the blood glucose monitoring mode. Specifically, in the currently preferred embodiments of the invention, blood glucose monitor 16 operates in conjunction with data management unit 10 and handheld microprocessor unit 12 to: (a) perform a test or calibration sequence in which tests are performed to confirm that the system is operating properly; and, (b) perform the blood glucose test sequence in which

blood glucose meter 16 senses the user's blood glucose level. Suitable calibration procedures for blood glucose monitors are known in the art. For example, blood glucose monitors often are supplied with a "code strip," that is inserted in the monitor and results in a predetermined value being displayed and stored in memory at the conclusion of the code strip calibration procedure. When such a code strip calibration procedure is used in the practice of the invention, the procedure is selected from one of the system menus. For example, if the system main menu includes a "monitor" menu item, a submenu displaying system calibration options and an option for initiating the blood glucose test may be displayed when the monitor menu item is selected. When a code strip option is available and selected, a sequence of instructions is generated and displayed by display screen 28 of handheld microprocessor unit 12 to prompt the user to insert the code strip and perform all other required operations. At the conclusion of the code strip calibration sequence, display unit 28 of handheld microprocessor unit 12 displays a message indicating whether or not the calibration procedure has been successfully completed. For example, FIGURE 4 illustrates a screen display that informs the system user that the calibration procedure was not successful and that the code strip should be inserted again (i.e., the calibration procedure is to be repeated). As is indicated in FIGURE 4, display screens that indicate a potential malfunction of the system include a prominent message such as the "Attention" notation included in the screen display of FIGURE 4.

As previously indicated, the blood glucose test sequence that is employed in the currently preferred embodiment of the invention is of the type in which a test strip is inserted in a receptacle that is formed in the blood glucose monitor. A drop of the user's blood is then applied to the test strip and a blood glucose sensing sequence is initiated. When the blood glucose sensing sequence is complete, the user's blood glucose level is displayed.

In the practice of the invention, program instructions stored in data management unit 10 (e.g., system ROM 90 of FIGURE 3) and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 cause the system to display step-by-step monitoring instructions to the system user and, in addition, preferably result in display of diagnostic messages if the test sequence does not proceed in a normal fashion. Although currently available self-contained microprocessor base blood glucose monitors also display test instruction and diagnostic messages, the invention provides greater message capacity and allows multi-line instructions and diagnostic messages that are displayed in easily understood language rather than cryptic error codes and abbreviated phraseology that is displayed one line at a time. For example, as is shown in FIGURE 5, the complete results of a blood glucose test (date, time of day, and blood glucose level in milligrams per deciliter) can be concurrently displayed by display screen 28 of handheld microprocessor unit 12 along with an instruction to remove the test strip from blood glucose monitor 16. As previously mentioned, when the blood glucose test is complete, the time and date tagged blood glucose test result is stored in the memory circuits of data management unit 10 (e.g., stored in EEPROM 94 of FIGURE 3).

The arrangement shown and described relative to FIGURES 1-3 also is advantageous in that data relating to food intake, concurrent medication dosage and other conditions easily can be entered into the system and stored with the time and date tagged blood glucose test result for later review and analysis by the user and/or his or her healthcare professional. Specifically, a menu generated by the system at the beginning or end of the blood glucose monitoring sequence can include items such as "hypoglycemic" and "hyperglycemic," which can be selected using the switches of handheld microprocessor unit 12 (e.g., operation of control pad 30 and switch 36 in FIGURE 1) to indicate the user was experiencing hypoglycemic or hyperglycemic symptoms at the time

of monitoring blood glucose level. Food intake can be entered in terms of "Bread Exchange" units or other suitable terms by selecting a "food intake menu item and using a submenu display and the switches of handheld microprocessor 12 to select and enter the appropriate information. A similar menu item - submenu selection process also can be used to enter medication data such as the type of insulin used at the time of the glucose monitoring sequence and the dosage.

As was previously mentioned, program instructions stored in data management unit 10 and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 enable the system to display statistical and trend information either in a graphic or alphanumeric format. As is the case relative to controlling other operational aspects of the system, menu screens are provided that allow the system user to select the information that is to be displayed. For example, in the previously discussed embodiments in which a system menu includes a "display" menu item, selection of the menu item results in the display of one or more submenus that list available display options. For example, in the currently preferred embodiments, the user can select graphic display of blood glucose test results over a specific period of time, such as one day, or a particular week. Such selection results in displays of the type shown in FIGURES 6 and 7, respectively. When blood glucose test results for a single day are displayed (FIGURE 6), the day of the week and date can be displayed along with a graphic representation of changes in blood glucose level between the times at which test results were obtained. In the display of FIGURE 6, small icons identify points on the graphic representation that correspond to the blood glucose test results (actual samples). Although not shown in FIGURE 6, coordinate values for blood glucose level and time of day can be displayed if desired. When the user chooses to display a weekly trend graph (FIGURE 7), the display generated by the system is similar to the display of a daily graph,

having the time period displayed in conjunction with a graph that consists of lines interconnecting points that correspond to the blood glucose test results.

The screen display shown in FIGURE 8 is representative of statistical data that can be determined by the system of FIGURE 1 (using conventional computation techniques) and displayed in alphanumeric format. More specifically, the exemplary screen display of FIGURE 8 provides statistical data for blood glucose levels over a period of time (e.g., one week) or, alternatively, for a specified number of monitoring tests. In the exemplary display of FIGURE 8, the system calculates and displays the average blood glucose level and the standard deviation. Displayed also is the number of blood glucose test results that were analyzed to obtain the average and the standard deviation; the number of test results under a predetermined level (50 milligrams per deciliter in the screen display shown in FIGURE 8); and the number of blood glucose tests that were conducted while the user was experiencing hypoglycemic symptoms. As previously noted, in the preferred embodiments of the invention, a screen display that is generated during the blood glucose monitoring sequence allows the user to identify the blood sample being tested as one taken while experiencing hyperglycemic or hypoglycemic symptoms and, in addition, allows the user to specify other relevant information such as food intake and medication information.

The currently preferred embodiments of the invention also allow the user to select a display menu item that enables the user to sequentially address, in chronological order, the record of each blood glucose test. As is indicated in FIGURE 9, each record presented to the system user includes the data and time at which the test was conducted, the blood glucose level, and any other information that the user provided. For example, the screen display of FIGURE 9 indicates that the user employed handheld microprocessor unit 12 as an interface to enter data indicating use of 12.5 units of regular

insulin; 13.2 units of "NPH" insulin; food intake of one bread exchange unit; and pre-meal hypoglycemic symptoms.

Use of data management unit 10 in conjunction with handheld microprocessor unit 12 also allows display of blood glucose test results along with food intake and/or medication information. For example, shown in FIGURE 10 is a daily graph in which blood glucose level is displayed in the manner described relative to FIGURE 6. Related food intake and medication dosage is indicated directly below contemporaneous blood glucose levels by vertical bar graphs.

It will be recognized by those skilled in the art that the above-described screen displays and system operation can readily be attained with conventional programming techniques of the type typically used in programming microprocessor arrangements. It also will be recognized by those skilled in the art that various other types of screen displays can be generated and, in addition, that numerous other changes can be made in the embodiments described herein without departing from the scope and the spirit of the invention.

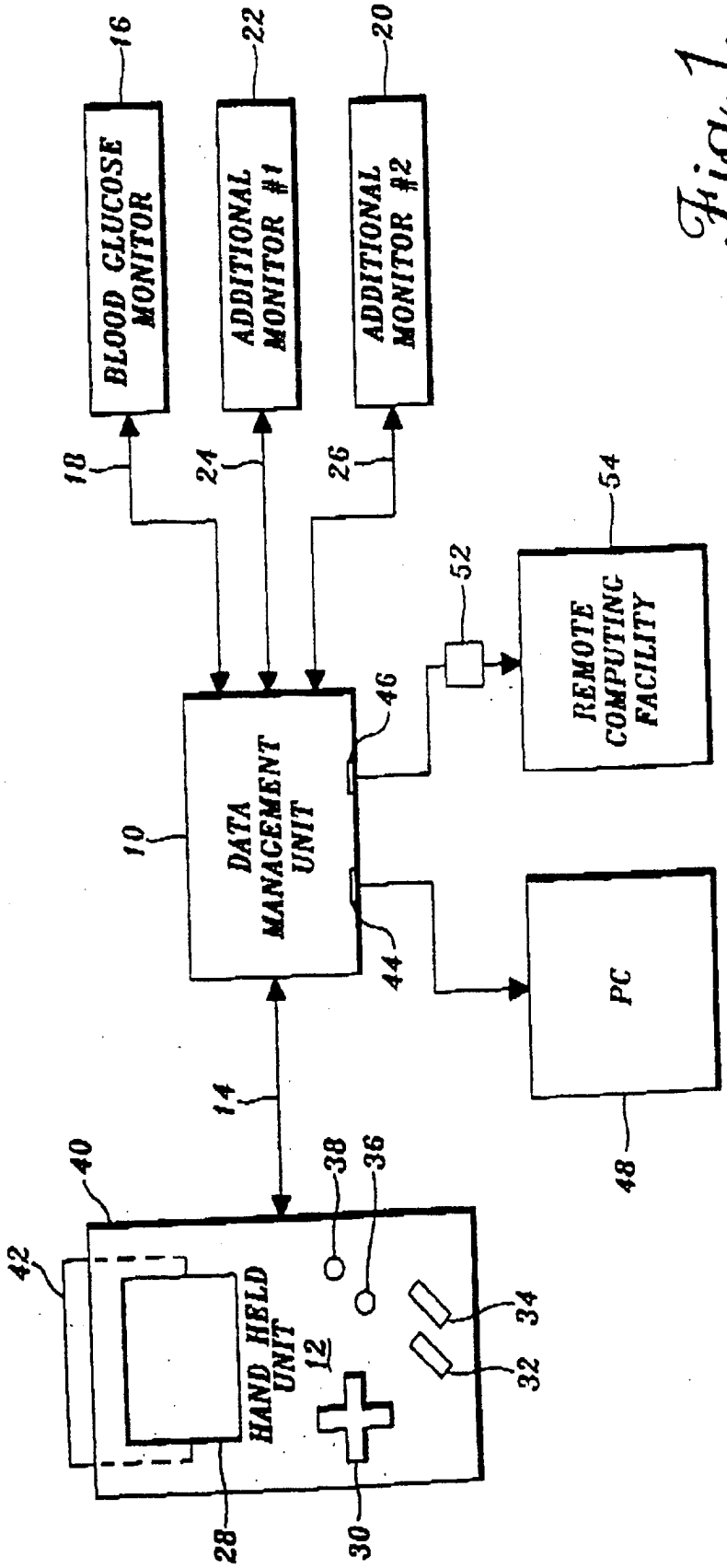

BLOOD GLUCOSE MONITOR
16
ADDITIONAL MONITOR #1
22
ADDITIONAL MONITOR #2
20
18
24
26
52
54
REMOTE COMPUTING FACILITY
DATA MANAGEMENT UNIT
10
46
44
PC
48
14
40
38
36
42
HAND HELD UNIT
12
34
32
28
30

Fig. 1.

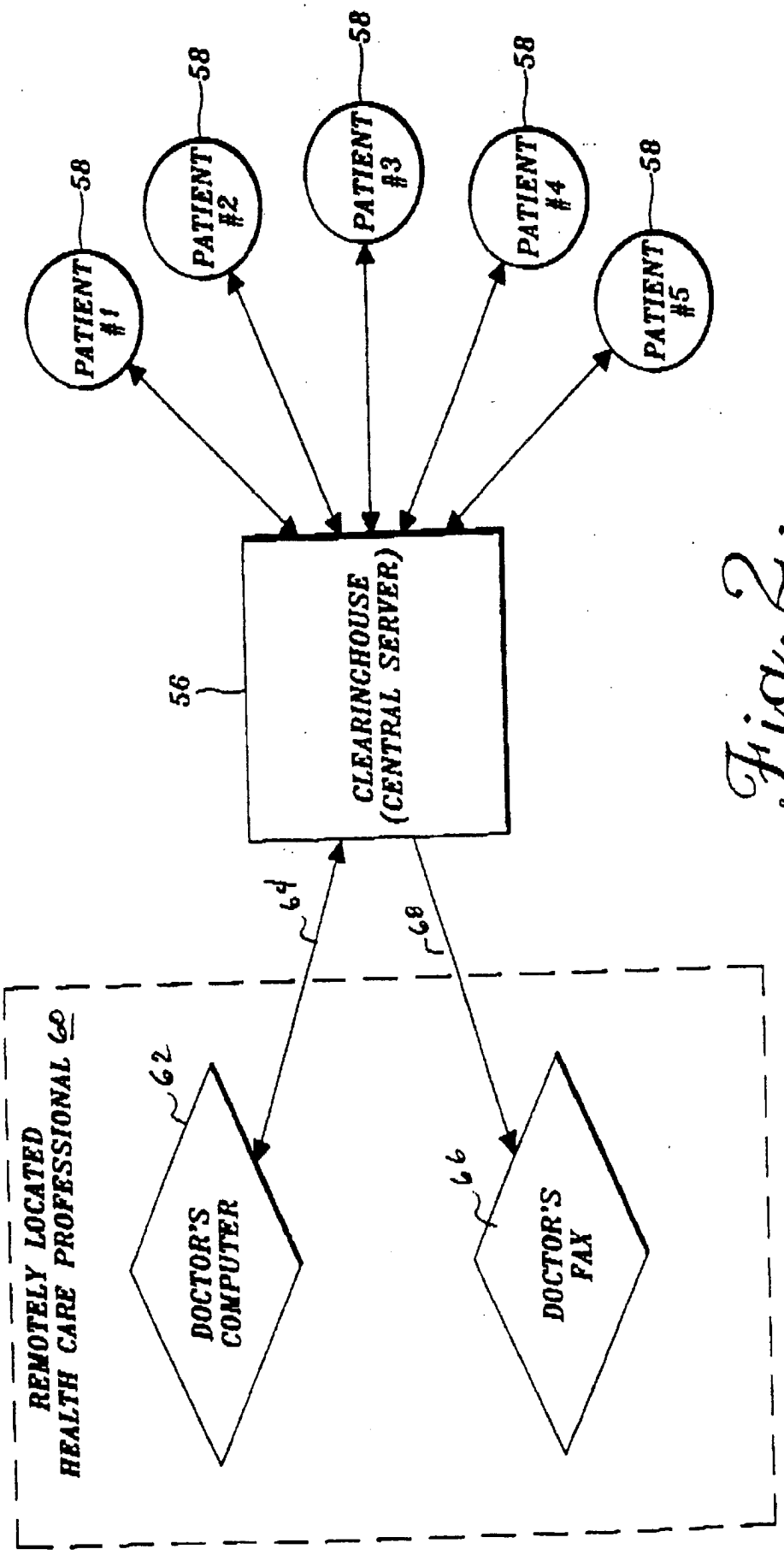
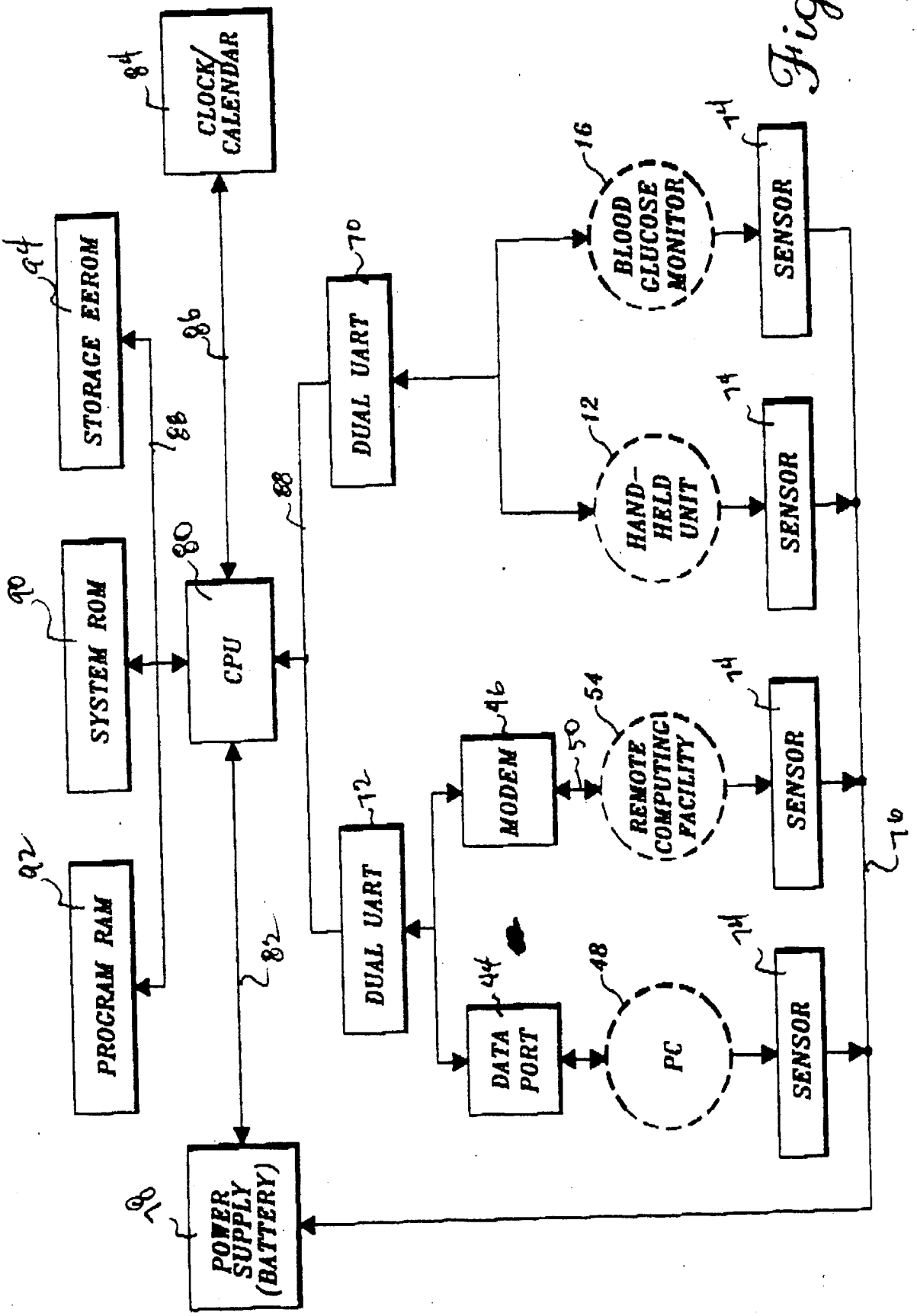

PATIENT #1
PATIENT #2
PATIENT #3
PATIENT #4
PATIENT #5
58
CLEARINGHOUSE (CENTRAL SERVER)
56
64
68
REMOTELY LOCATED HEALTH CARE PROFESSIONAL 60
DOCTOR'S COMPUTER
62
DOCTOR'S FAX
66

Fig. 2.


CLOCK/ CALENDAR
STORAGE EEROM
SYSTEM ROM
PROGRAM RAM
CPU
POWER SUPPLY (BATTERY)
DUAL UART
DUAL UART
MODEM
DATA PORT
PC
REMOTE COMPUTING FACILITY
HAND-HELD UNIT
BLOOD GLUCOSE MONITOR
SENSOR
SENSOR
SENSOR
SENSOR
SENSOR
84
94
96
90
80
92
82
98
88
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54
12
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74
74
74
74
74
76

Fig. 3.

Fig.4.

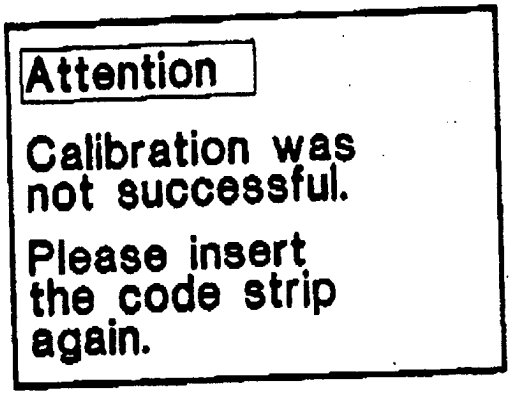


Fig.5.

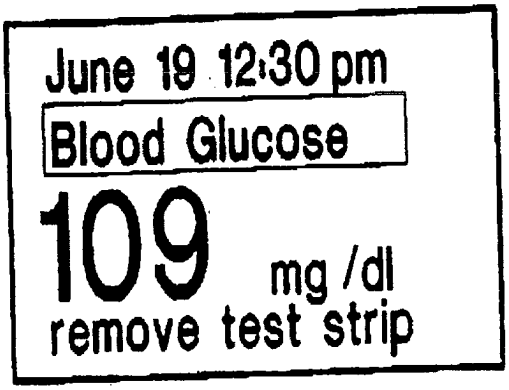


Fig.6.

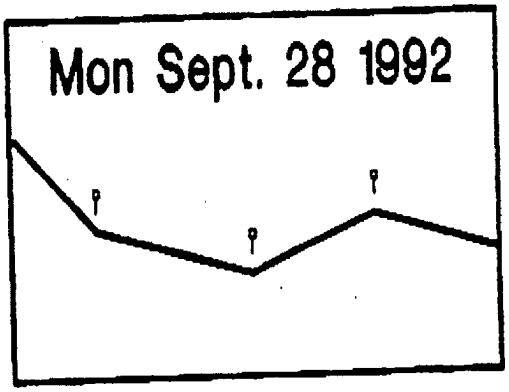


Fig.7.

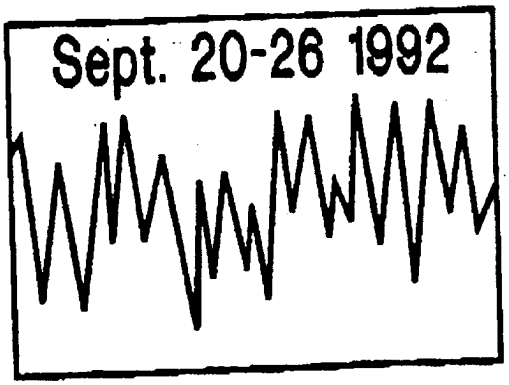


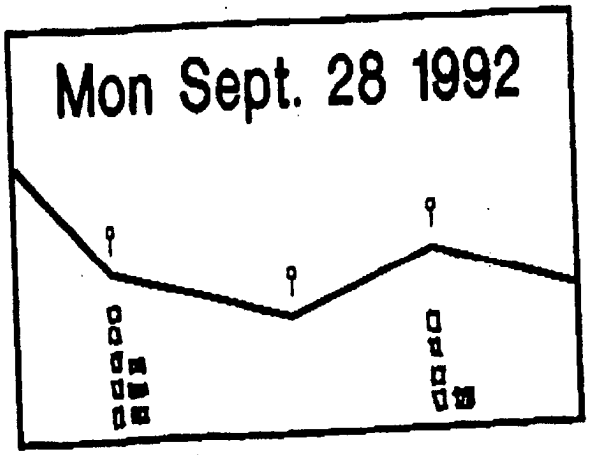
Fig. 8.

Glucose
Ave: 123 mg/dl
SD: 56
Num: 15
No. under 50: 13
No. hypo sym: 23

Fig. 9.

June 12 9:30pm
BG 113 mg/dl
Regin 12.5 U
NPHin 13.2 U
Food 1 BE
Pre-meal HYPO

Fig. 10.



Facsimile Cover Sheet

To: Mr. James Anable Esq.
Company: Christiansen O'Connor
Phone: (206) 682-8100
Fax: (206) 224-0779

From: Steve Brown
Company: Raya Systems, Inc
Phone: (415) 949-3933
Fax: (415) 949-3935

Healthboy

Date: 10/02/92
Pages including this cover page: 3

Comments:

******* PANAFAX 155 *** -JOURNAL- ********** DATE 01/17/1900 ***** TIME 16:07 ********

NO.	COM	DOC	DURATION	X/R	IDENTIFICATION	DATE	TIME	DIAGNOSTIC
28	OK	03	00:01'35	XMT	GROUP3	01/17	16:05	020440AC0800

********** -PANASONIC- ********** - - *********

October 2, 1992

Mr. James Anable Esq.
Christiansen O'Connor
2800 Pacific First Center
1420 Fifth Avenue
Seattle, WA 98101

Dear James:

I am faxing you the diagram which shows the basic system. I am worried about focusing on the particulars and losing the fundamentals, and I think this diagram needs to be in the application.

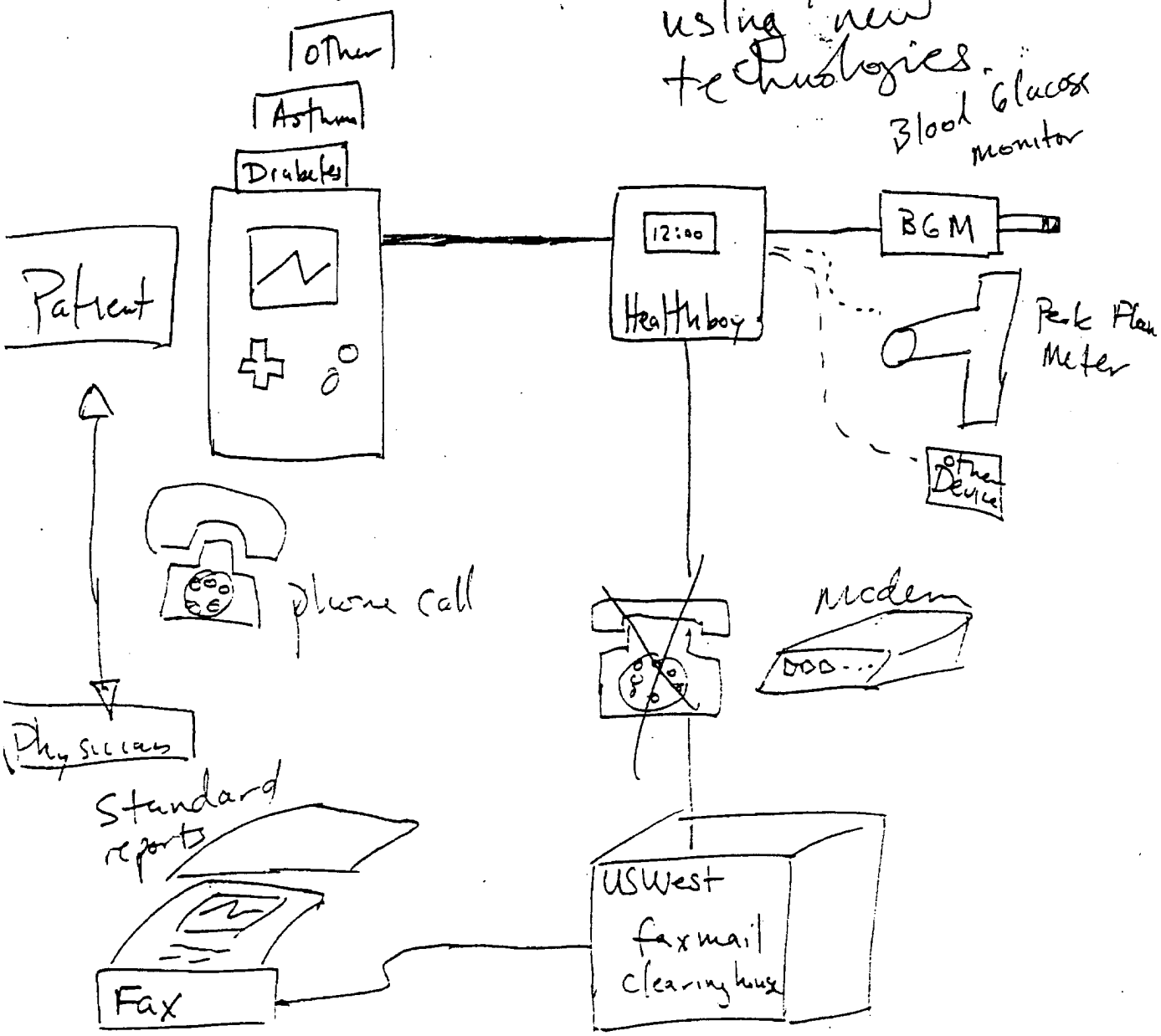
Sincerely,

Steve Brown
President

raya systems

Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040
phone: (415) 949-3933
fax: (415) 949-3935

The System — Link Juvenile Patients to Physicians using new technologies.



CHRISTENSEN, O'CONNOR,
JOHNSON & KINDNESS
2800 Pacific First Centre
1420 Fifth Avenue
Seattle, WA 98101
(206) 682-8100

RAYA SYSTEMS, INC.

OCTOBER 31 1992

2570 WEST EL CAMINO REAL
SUITE 309
MT. VIEW, CA 94040

---

nvoice # 632084

or Services And Disbursements
**** RAYA-6631
1>MODULAR MICROPROCESSOR...
US PATENT APP

Services

OCT 01 92 JWA	Work on patent application	6.80		1,496.00
OCT 02 92 JWA	Review S. Brown comments regarding patent application draft; Review and revise patent application	1.40		308.00
OCT 07 92 JWA	Meeting with S. Brown; Work on patent application	4.90		1,078.00
OCT 27 92 JWA	Review and revise patent application	2.30		506.00
OCT 28 92 JWA	Review and revise patent application	1.50		330.00
OCT 29 92 JWA	Review and revise patent application	1.50		330.00
OCT 29 92 JM	Work on patent drawings	1.30		65.00
	Total Hours	19.70		
	Total Fees			4,113.00

Disbursements

OCT 19 92 FIRM	Telecopier handling charge	2.00	
	Photocopies	9.30	
	Long distance telephone charges	6.96	
	Total Disbursements		18.26

nable James W	JWA	PTNR	18.40	220.00	4,048.00	
lez Joel	JM	ILLU	1.30	50.00	65.00	
		ILLU	1.30	50.00	65.00	
		PTNR	18.40	220.00	4,048.00	

Disbursements

Continued

CHRISTENSEN, O'CONNOR,
JOHNSON & KINDNESS
2800 Pacific First Centre
1420 Fifth Avenue
Seattle, WA 98101
(206) 682-8100

RAYA SYSTEMS, INC. NOVEMBER 30 1992
\
2570 WEST EL CAMINO REAL
SUITE 309
MT. VIEW, CA 94040

PAGE 2

:nvoice # 636008

:or Services And Disbursements
:**** RAYA-6631
1>MODULAR MICROPROCESSOR...
US PATENT APP SN 977,323 11/17/92
BROWN SJ

Services

NOV 05 92 JM	Work on patent drawings	.40		20.00
NOV 17 92 JM	Work on patent drawings	.60		51.00
	Total Hours	1.00		
	Total Fees			71.00

Disbursements

NOV 11 92 FIRM	Telecopier handling charge	5.00	
	Long distance telephone charges	.47	
	Total Disbursements		5.47

lez Joel	JM	ILLU	1.00	71.00	71.00	
		ILLU	1.00	71.00	71.00	

Disbursements

	Long distance telephone charges	.47	
	Telecopier handling charge	5.00	
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	Total Fees		71.00
	Total Disbursements		5.47

			$76.47

:nvoice due upon receipt. Interest charged at 1.50% per month from invoice date on amounts unpaid 45 days after invoice date.
:hristensen, O'Connor, Johnson & Kindness--Tax I.D. No. 91-0860813
)005

PTO-103X
(rev. 11-86)

FILING RECEIPT

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

EXHIBIT AB
PAGE 1 OF 1

SERIAL NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
07/977,323	11/17/92	2311	$ 420.00	RAYA-1-6631	5	12	1

CHRISTENSEN, O'CONNOR,
JOHNSON & KINDNESS
2800 PACIFIC FIRST CENTRE
1420 FIFTH AVE.
SEATTLE, WA 98101

Receipt is acknowledged of the patent application identified herein. It will be considered in its order and you will be notified as to the examination thereof. Be sure to give the U.S. SERIAL NUMBER, DATE OF FILING, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this transmittal.

Applicant(s)

STEPHEN J. BROWN, PALO ALTO, CA.

FOREIGN FILING LICENSE GRANTED 03/11/93 * SMALL ENTITY *

TITLE
MODULAR MICROPROCESSOR-BASED HEALTH MONITORING SYSTEM

PRELIMINARY CLASS: 364

RECEIVED
MAR 22 1993
Christensen, O'Connor
Johnson & Kindness

(see reverse)

OIPE JC42
JUL 06 2004
PATENT & TRADEMARK OFFICE

Attorney's Docket No. 6858P001X4 Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Stephen J. Brown

Application No.: 09/237,194

Filed: January 26, 1999

For: REMOTE HEALTH-MONITORING SYSTEM WITH NETWORKED SERVER AND HEALTH CARE PROFESSIONAL

Examiner: Kalinowski, Alexander G.

Art Group: 3626

RECEIVED
JUL 8 2004
GROUP 3600

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION/AFFIDAVIT OF PRIOR INVENTION IN THE UNITED STATES TO OVERCOME CITED PATENT OR PUBLICATION (37 C.F.R. § 1.131)

Dear Commissioner:

1. My name is Stephen J. Brown and I am the sole inventor of the subject matter claimed in patent application USSN 09/237,194 ("this patent application").

2. This is an affidavit under 37 CFR § 1.131 showing conception of the invention claimed in this patent application prior to the effective date of the reference cited by the Examiner. Conception of the invention was coupled with due diligence from prior to the effective date of the earliest application from which the present application claims priority (USSN 07/977,323, filed November 17, 1992).

3. The effective date of US patent 5,390, 238 (Kirk et al.) is the date that it is effective as a reference under 35 U.S.C. 102(e), i.e., June 15, 1992.

4. **I invented the invention in this patent application before June 15, 1992.**

   a. As evidence, I attach, as Exhibit 1, a copy of a March 2, 1992 fax letter from me to Boerhringer Mannheim GmbH.

   b. The second paragraph of this fax describes the elements of Figure 1 of this patent application. For example, the data management unit 10 is mentioned, so too are the hand held unit 12 (video game), modem (52), communications with doctors at 56, and the fact that the doctor and patient are remote from each other (implicit in the words "home system which connects to the doctor").

   c. This system had been developed by the time the fax had been sent (as evidenced by the words "have developed") and, as illustrated by the fax itself, was in a form appropriate to discuss with potential buyers.

5. **This prior invention was coupled with due diligence until the application was filed.**

   a. On or before August 13, 1992 enough design work had been done to produce a schematic, a list of features and a hardware "wish list" for the invention (see Exhibit 2).

   b. Also, by August 13, 1992 enough work had been done to hire a hardware engineer as a consultant to implement the invention (see the NDA of Craig Nelson and handwritten notes, attached as Exhibit 3).

   c. On or before August 14, 1992 a basic hardware design (see 2-page Exhibit 4) existed.

   d. All the documents in Exhibits 2 to 4 were sent on August 14, 1992 to an attorney for the purposes of preparing a patent application (see Jack Thornton's fax cover sheet to Richard Black attached a Exhibit 5).

   e. By September 3, 1992 attorney Jim Anable had been instructed to prepare the patent application (see Exhibit 6).

   f. A retainer of $6,000 was paid to the attorney's firm, Christensen O'Conner, et al on or around September 15, 1992 (see Exhibit 7).

g. Attorney Anable sent a first draft of this patent application to me for review as inventor on October, 2 1992 (see Exhibit 8).

h. On that same day, I faxed to the attorney a drawing of the invention that should have been in the application (see Exhibit 9).

i. Christensen O'Conner, et al continued to work on the application during the months of October and November until the effective filing date of this application. (See Christensen O'Conner, et al billings attached as xhibit 10)

j. The application was filed on November 17, 1992 as USSN 07/977,323, an application from which this application 09/237, 194 claims priority.

6. Based on the above and as is evident from the attached exhibits, the invention and reduction to practice of the subject matter described in this application was prior to the effective date of US patent 5,390, 238 (Kirk et al.) i.e., June 15, 1992.

7. As the below signed inventor, I, Stephen J. Brown, hereby declare that all statements herein are of my own knowledge and are true and that all statements made on information and belief are believed to be true; and further that these statements are made knowing that willful false statements and the like are punishable by fine or imprisonment, or both under § 1001 of Title 18 of the United States Code, and such willful and false statements may jeopardize the validity of the application or any patent issuing on the application.

Very Truly yours,

Dated: June 28, 2004

Full Legal Name: Stephen J. Brown
Citizenship: U.S.A.
Address: 3324 Woodside Road, Woodside, California

Exhibit 1

Date March 2, 1992

To Dr. Norbert Jersch
Dr. Thomas Keiser
Central Marketing Patient Systems
Boehringer Mannheim GmbH
fax (011 49 621) 759 4179

From Steve Brown
Raya Systems
Mountain View, CA
fax (415) 949 3935

re Camit, Diabcare

Thank you for the order for Camit 2.5. We accept the conditions, except that we would like to start development on April 6, rather than March 1. As I discussed with Hartmut, it makes more sense for us start closer to the time when a prototype will be available. I want to devote continuous attention to the project until completion, rather than doing some development now and then waiting for the prototype EL.

With regard to Diabcare, I would like to have a new agreement confirming our fax transmittals of the last two months.

I have developed an interface for the Camit EL to a Nintendo video game machine, and am producing a data management program for the Super Nintendo Entertainment System. In the United States, Nintendo video game computers are in 40 million homes. They are inexpensive and attach to television sets. Raya Systems is licensed by Nintendo to produce such a product, and I hope to discuss the possibilities with BM USA. Can you tell me who to contact there? This could be an ideal platform for a home system which connects to the doctor system (Camit) via modem.

Sincerely,

Steve Brown

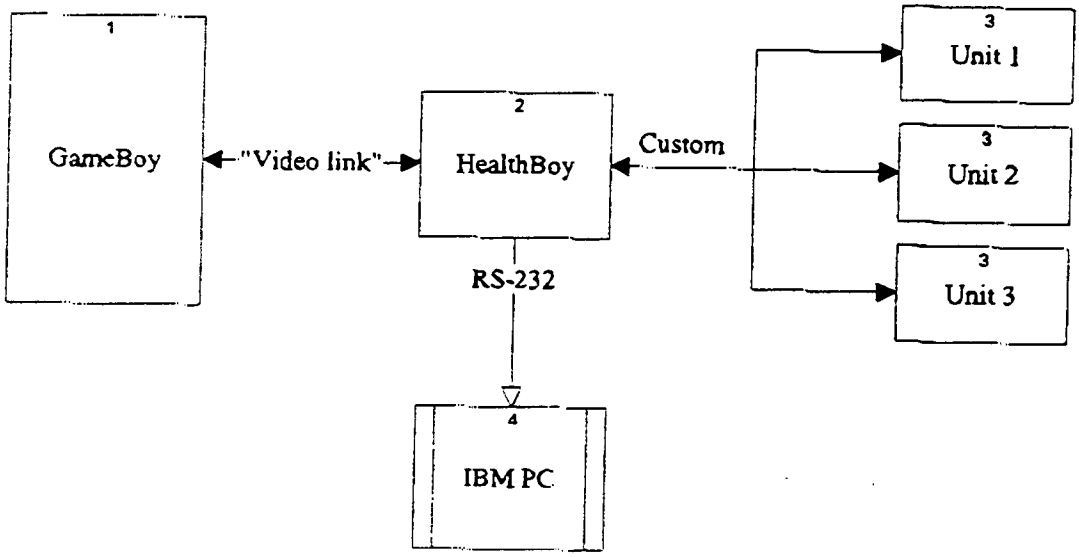
rayasystems

HealthBoy Project

TopChart

Thursday, August 13, 1992

11:46 AM



CONFIDENTIAL

HealthBoy features:

- *Communicate to GameBoy via serial "Video-Link" (multi-player) cable*
- *Communicate to multiple external devices (e.g. diabetes blood-sugar meter) via custom hookup*
- *Dump data to external computers (e.g. IBM PC) via RS-232 (9-pin connector)*
- *Clock/Calendar capability for time/date stamp of samples*
- *Internal battery backed-up RAM for storage of samples*
- *Low-power microprocessor*
- *Input connectors designed to be "user stupid"/hard to damage*
- *GameBoy cartridges for each external device for display of data*

Hardware wish list:

- *Microprocessor with multiple interrupt levels*
- *Hardware-driven communications with GameBoy with buffer*
- *Automatic RS-232 buffer*
- *Hardware-driven communications with external devices with buffer*
- *Large amount of RAM for long-term storage of samples*

CONFIDENTI

Exhibit 3

CONFIDENTIAL

rayasystems

Non-Disclosure Agreement

This agreement is made to be effective the 13th day of August, 1992 by and between Craig Nelson and Raya Systems, Inc., 2570 West El Camino Real, Suite 309, Mountain View, CA 94040, hereinafter referred to as "PARTIES."

The "PARTIES" agree that, with respect to any confidential information disclosed by one PARTY to the other, both PARTIES will apply and honor the mutual covenants and promises described below:

(1) "Confidential Information" shall be any and all information which is in fact confidential and proprietary to the disclosing PARTY and which the disclosing PARTY designates as confidential at the time such disclosure is made;

(2) The non-disclosing PARTY shall not disclose or cause to be disclosed, in whole or in part, any such Confidential Information to any third party without the prior written consent of the disclosing PARTY, except where:

(a) at the time of disclosure, the Information is publicly known, or was already known (as evidenced by documents) by the non-disclosing PARTY, or

(b) after disclosure to a PARTY, such information becomes publicly known through no fault of the PARTIES, or

(c) disclosure is required by law or governmental agency or any subdivision thereof, or

(d) seven (7) years have elapsed from the date upon which disclosure is made;

(3) In the event that either of the PARTIES breaches this agreement, the breaching PARTY shall be liable for any and all losses resulting from said breach which are incurred by the non-breaching PARTY.

8/13/92
Date

By: Craig Nelson

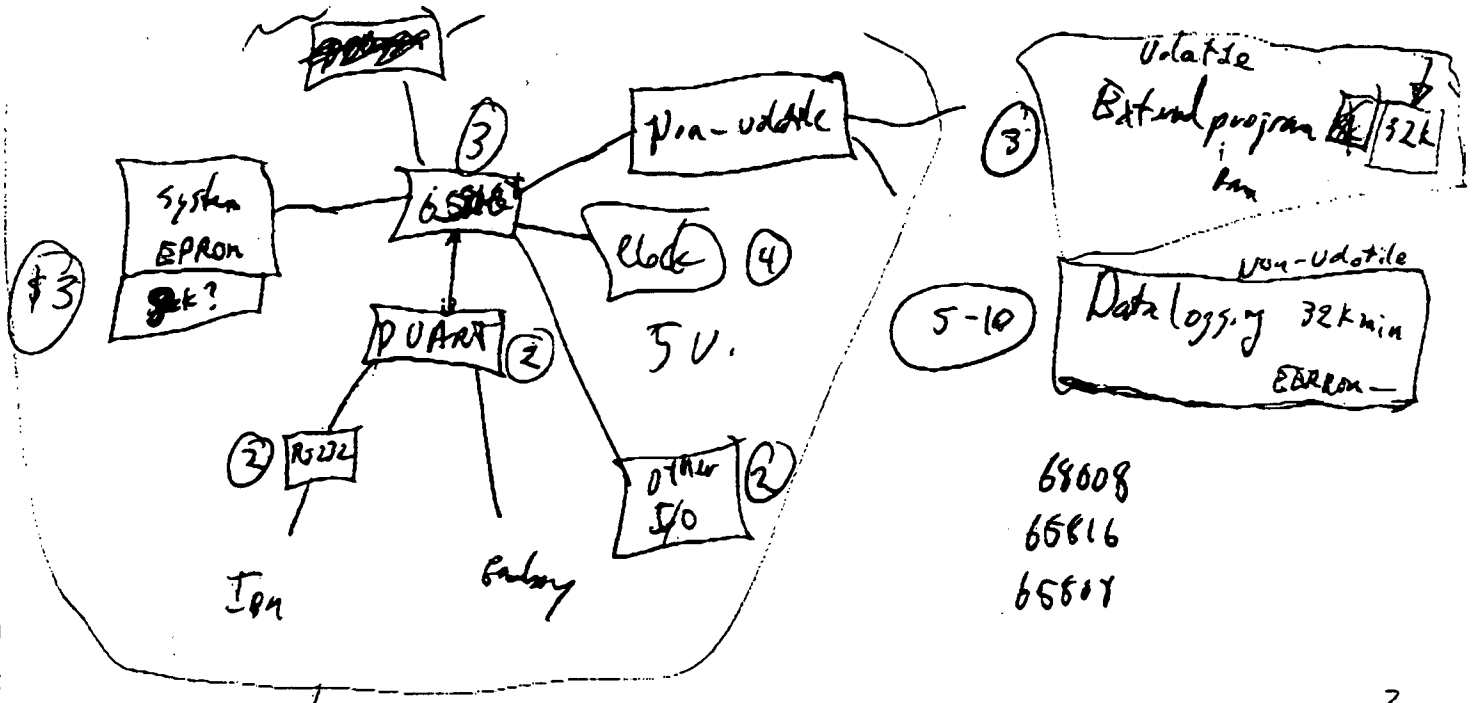
8/13/92
Date

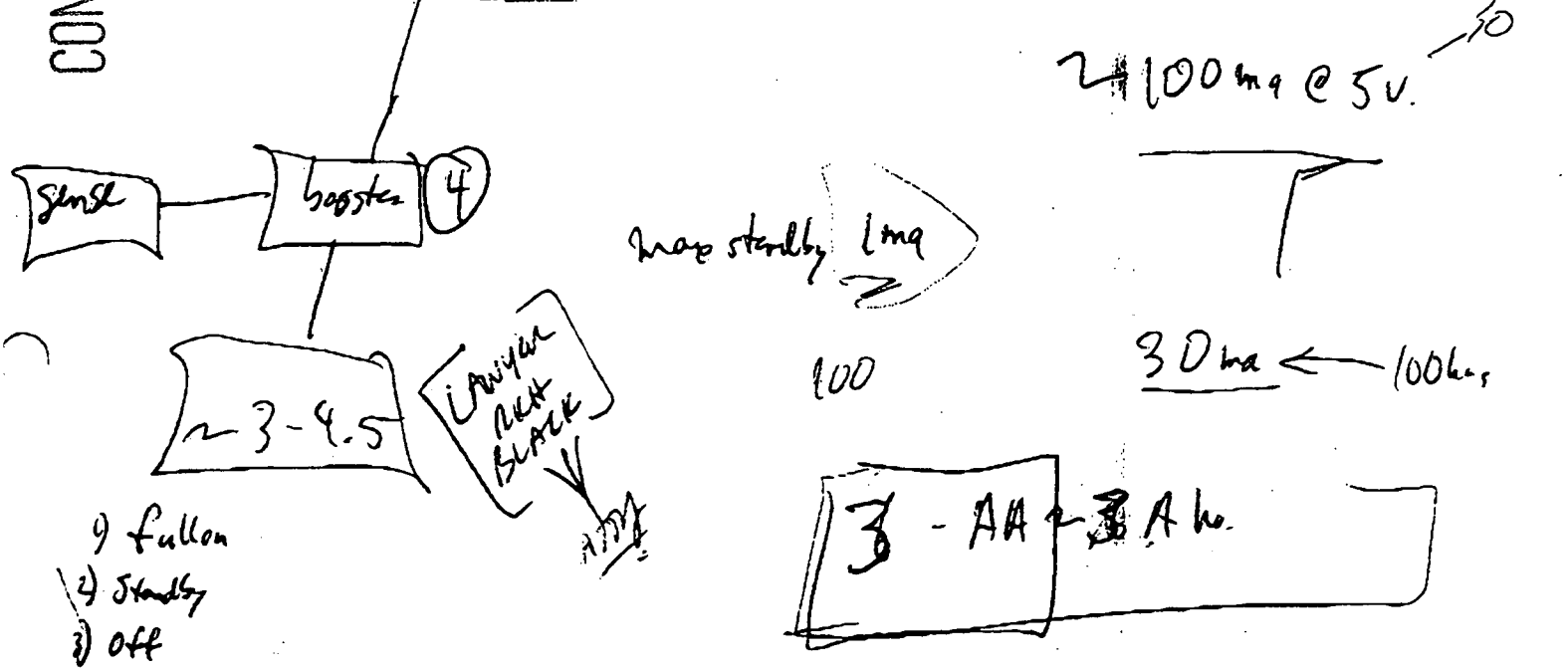
RAYA SYSTEMS, INC.

By: Jack Thornton
Director of Product Development

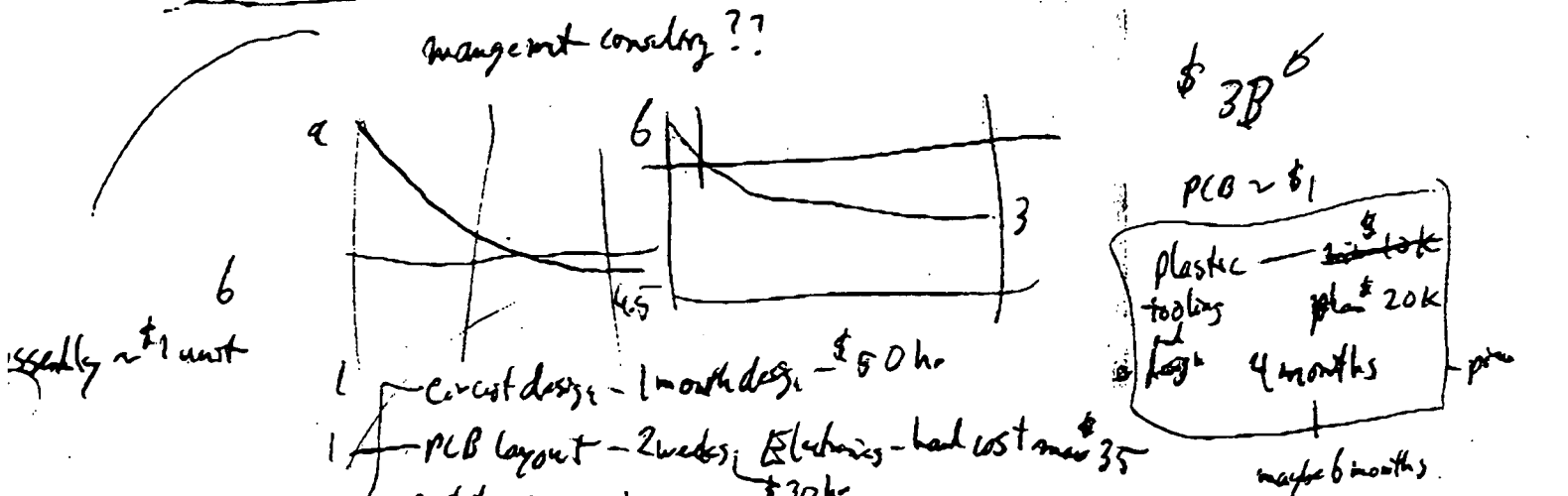
CONFIDENTIAL

CONFIDENTIAL





Lyon 6AA — 500ma — 5hrs



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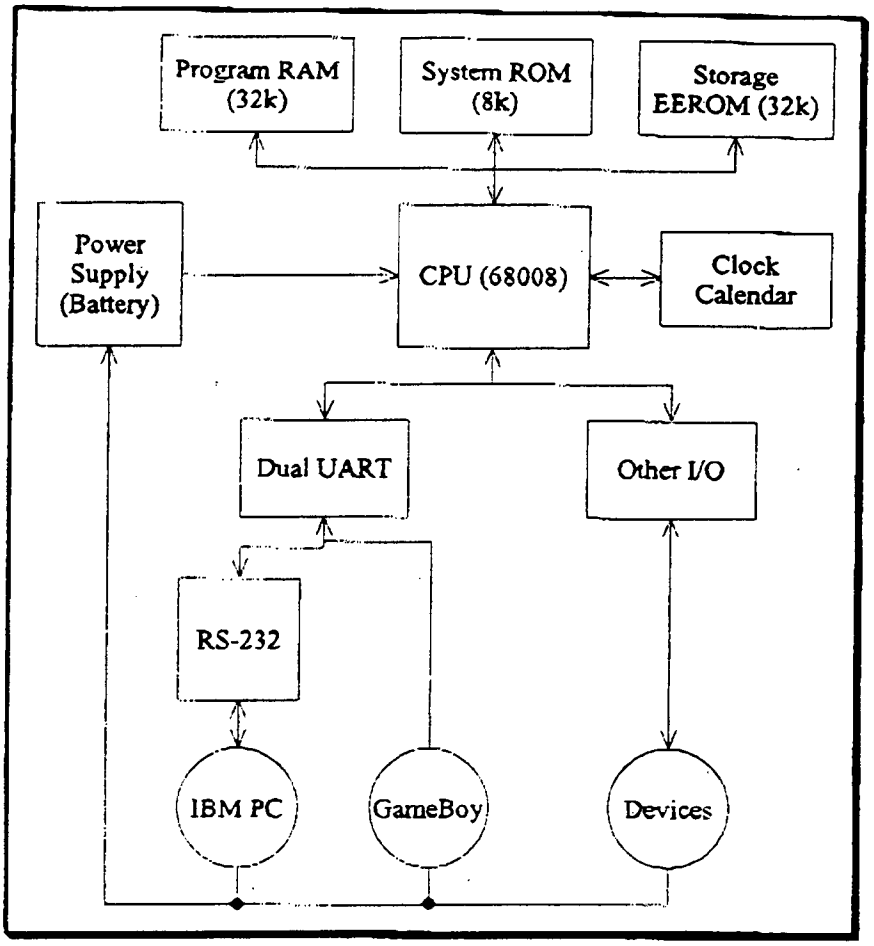

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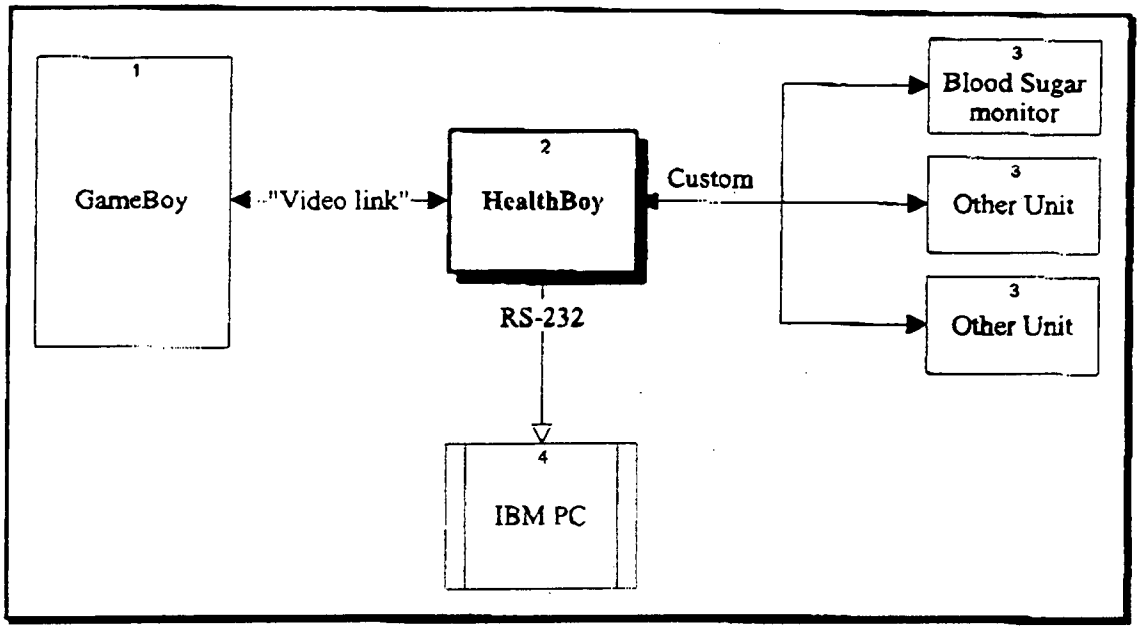
Development Cost (estimates)

Description	Units	Unit type	Rate	% use	Brdn Rate	Cost
Hardware design/test	6	weeks	$2,000.00	100%	100%	$12,000.00
Hardware prototyping	4	weeks	$800.00	100%	100%	$3,200.00
Circuit board design	2	weeks	$1,200.00	100%	100%	$2,400.00
Plastic design & development	4	months				$20,000.00
Software design	4	weeks	$1,000.00	100%	125%	$5,000.00
Software implement/test	6	weeks	$1,000.00	100%	125%	$7,500.00
Management	14	weeks	$1,084.62	10%	125%	$1,898.08
Clerical	14	weeks	$538.46	5%	125%	$471.15
Photocopy/Supplies	14	weeks	$10.00	100%	100%	$140.00
Telephone	14	weeks	$10.00	100%	100%	$140.00
Shipping						$300.00
GameBoy Develop. system						$13,000.00
IBM PC System						$2,500.00
Estimated costs						$68,549.23
Reserve (15%)						$10,282.38
Total development budget						$78,831.62

Note:
Another option is to build our own custom chip to perform most of the functions of the separate parts specified in the design.
Advantages:

Functional design / features



Basic hardware design

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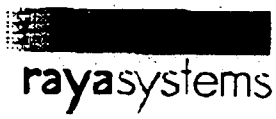
Exhibit 5

FAX LETTER



Raya Systems, Inc.
2570 West El Camino Real, Suite 309, Mountain View, California 94040
Phone (415) 949-3933 Fax (415) 949-3935

TO:	Richard T. Black
COMPANY:	Oles, Morrison & Rinker
FAX NUMBER:	(206) 682-6234
FROM:	Jack Thornton
DATE:	August 14, 1992
RE:	HealthBoy project - potential patent application
NUMBER OF PAGES:	7, including this one
CC:	Steve Brown

CONFIDENTIAL

I have been instructed by Steve Brown to forward notes about the HealthBoy project to you for the purposes of a possible patent application. I met with a hardware engineer yesterday, and based on that information I have a very preliminary design of the central module with cost estimates. Included in this fax are my notes, the engineer's (Craig Nelson's) handwritten notes, and the non-disclosure agreement signed by Craig.

As more information is developed, I will be forwarding it to you.

If you have any questions, please feel free to give me a call.

RECEIVED
8:15 am
AUG 14 1992
OLES, MORRISON & RINKER

Sincerely,

Jack Thornton
Director of Product Development
Educational Software

CONFIDENTIAL

Exhibit 6

OLES, MORRISON & RINKER
LAWYERS

3300 COLUMBIA CENTER
701 FIFTH AVENUE
SEATTLE, WASHINGTON 98104-7007
(206) 623-3427
TELECOPIER: (206) 682-6234

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DAVID C. STEWART
SAM E. BAKER, JR.
ARTHUR D. McGARRY
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THEODORE L. PREG
WILLIAM G. JEFFERY
ROBERT J. BURKE
DAVID H. KARLEN

BRADLEY L. POWELL
DOUGLAS S. OLES
PETER N. RALSTON
MICHELE M. SALES
MARK F. O'DONNELL
JOHN LUKJANOWICZ
DAVID R. TRACHTENBERG
JAMES F. NAGLE
KRIS J. SUNDBERG

RICHARD T. BLACK
TIM W. DORE
MICHAEL H. FERRING
HARLAN M. HATFIELD
T. DANIEL HEFFERNAN
EVALYN K. HODGES
JON G. HONGLADAROM
JOHN F. JENKEL

TRAEGER MACHETANZ
GLENN R. NELSON
TODD M. NELSON
JOHN V. OHNSTAD, JR.
BRIAN E. ONORATO
J. CRAIG RUSK
ROBERT W. SARGEANT

STUART G. OLES
OF COUNSEL

GERALD DE GARMO
(1903-1988)

September 3, 1992

VIA FAX

Mr. Stephen Brown
Raya Systems, Inc.
2570 West El Camino Real, Suite 309
Mt. View, CA 94040

RE: Patent Application

Dear Steve:

As per your instructions, we have authorized Jim Anable to begin work on your application. He and his office should be contacting you frequently in the next several weeks, and it is important that you and Jack respond promptly to his questions to expedite the process.

Normally, it is optimal to do a patentability search in advance of the application to minimize the risk of denial. You have asked that the search be deferred until later so that you can meet your Sept. 23rd deadline and to avoid the extra cost. After the meeting, you might want to do a search so that you can amend the application (to the extent possible) to better avoid the prior art, and so maximize the odds of patentability. If you could afford to, it would be best to pay for the patentability search now so that it could be done while your application is being developed, and the results incorporated into the application before filing. However, because of cost considerations, I will assume you are willing to bear the risk of omitting or deferring a patentability search.

Please call if you have any questions. I will be at (509) 663-2225 from Friday until Tuesday.

Very truly yours,

OLES, MORRISON & RINKER

Richard T. Black

Richard T. Black

cc: Douglas S. Oles

Exhibit 7

OLES, MORRISON & RINKER
LAWYERS

SETH W. MORRISON
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ARTHUR D. McGARRY
B. MICHAEL SCHESTOPOL
THEODORE L. PREG
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GLENN R. NELSON
J. CRAIG RUSK
JOHN F. JENKEL

STUART G. OLES
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EVALYN K. HODGES

JON G. HONGLADAROM
TRAEGER MACHETANZ
TODD M. NELSON
BRIAN E. ONORATO
ROBERT W. SARGEANT

September 15, 1992

James W. Anable, Esq.
Christensen, O'Connor, Johnson & Kindness
2800 Pacific First Center
1420 Fifth Avenue
Seattle, WA 98101

RE: Raya Systems, Inc.

Dear Jim:

Enclosed is Raya's check in the amount of $6,000 as a retainer for your work on Raya's patent. Please forward a receipt to Raya.

Very truly yours,

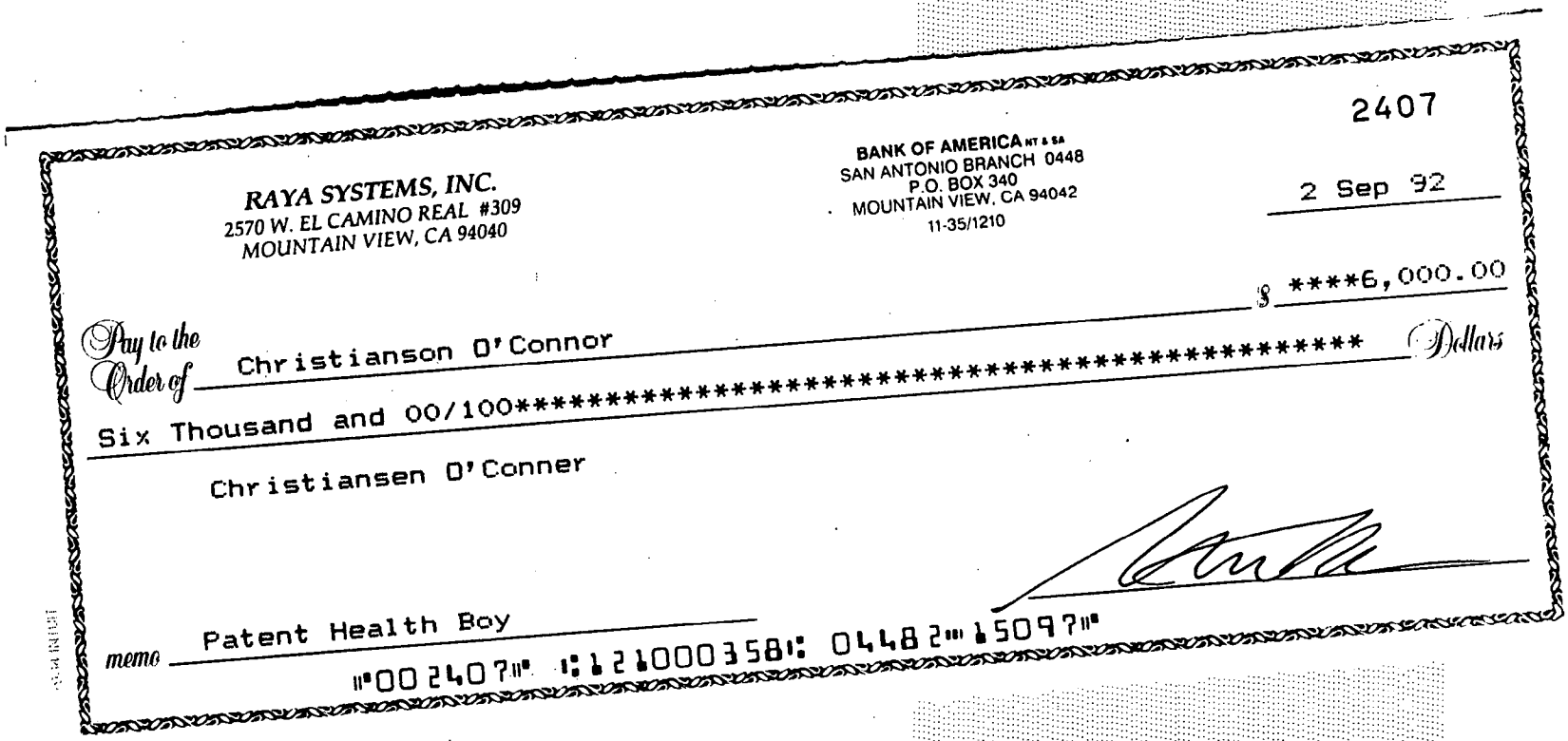
OLES, MORRISON & RINKER

Richard T. Black

Richard T. Black

RTB/jd
Enclosure
cc: Douglas Oles, Esq.

6228-001
RTB20915.001



2407

RAYA SYSTEMS, INC.
2570 W. EL CAMINO REAL #309
MOUNTAIN VIEW, CA 94040

BANK OF AMERICA NT & SA
SAN ANTONIO BRANCH 0448
P.O. BOX 340
MOUNTAIN VIEW, CA 94042
11-35/1210

2 Sep 92

Pay to the Order of Christianson O'Connor $ ****6,000.00

Six Thousand and 00/100********** Dollars

Christiansen O'Conner

memo Patent Health Boy

⑈002407⑈ ⑆121000358⑆ 04482⑈15097⑈

Exhibit 8

O'CONNOR JOHNSON KINDNESS

PATENT, TRADEMARK AND OTHER INTELLECTUAL PROPERTY MATTERS

FAX: (206) 224-0779
TELEX: 4938023
CABLE: PATENTABLE

FACSIMILE COVER SHEET

DATE: October 2, 1992

TO: Steve Brown/Jack Thornton

Raya Systems, Inc.

FACSIMILE NUMBER: (415) 949-3935

RE: Patent Application

OUR REFERENCE: RAYA-1-6631

YOUR REFERENCE:

FROM: James W. Anable, Esq.

(Facsimile No. (206) 224-0779 - Panafax Groups 1, 2 & 3)

MESSAGE:

Please review and contact me. I am out of the office this morning but expect to return by noon. I will await your call.

Enclosures: Patent Application (DRAFT) and drawings (DRAFT)

*** The information contained in this facsimile message is privileged and confidential information intended only for the use of the recipient named above. If the reader of this message is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, any distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return the original message to us at the above address by mail. ***

We have 34 pages to send, including this sheet. If any pages need to be retransmitted, please call (206) 682-8100, Ext. ____, within 15 minutes.

This document was transmitted at _____:_____ ___m.

MODULAR MICROPROCESSOR-BASED HEALTH MONITORING SYSTEM

Field of the Invention

This invention relates to administering and monitoring personal healthcare. More specifically, this invention relates to self-care health monitoring arrangements that enable a patient or other user to gather data important to a health management program and, if desired or necessary, easily provide that data to a healthcare professional.

Background of the Invention

Controlling or curing conditions of ill health generally involves both establishing a therapeutic program and monitoring the progress of the afflicted person. Based on that progress, decisions can be made as to altering therapy to achieve a cure or maintain the affliction or condition at a controlled level. Successfully treating certain health conditions calls for rather frequent monitoring and a relatively high degree of patient participation. For example, in order to establish and maintain a regimen for successful diabetes care, a diabetic should monitor his or her blood glucose level and record that information along with the date and time at which the monitoring took place. Since diet, exercise, and medication all affect blood glucose levels, a diabetic often must record data relating to those items of information along with blood glucose level so that the diabetic may more closely monitor his or her condition and, in addition, can provide information of value to

the healthcare provider in determining both progress of the patient and detecting any need to change the patient's therapy program.

Advances in the field of electronics over the past several years have brought about significant changes in medical diagnostic and monitoring equipment, including arrangements for self-care. With respect to the control and monitoring of diabetes, relatively inexpensive and relatively easy-to-use blood glucose monitoring systems have become available that provide reliable information that allows a diabetic and his or her healthcare professional to establish, monitor and adjust a treatment plan (diet, exercise, and medication). More specifically, microprocessor-based blood glucose monitoring systems are being marketed which sense the glucose level of a blood sample that is applied to a reagent-impregnated region of a test strip that is inserted in the glucose monitor. When the monitoring sequence is complete, the blood glucose level is displayed by, for example, a liquid crystal display (LCD) unit.

Typically, currently available self-care blood glucose monitoring units include a calendar/clock circuit and a memory circuit that allows a number of blood glucose test results to be stored along with the date and time at which the monitoring occurred. The stored test results (blood glucose level and associated time and date) can be sequentially recalled for review by the blood glucose monitor user or a health professional by sequentially actuating a push button or other control provided on the monitor. In some commercially available devices, the average of the blood glucose results that are stored in the monitor (or the average of the results for a predetermined period of time, e.g., fourteen days) also is displayed during the recall sequence. Further, some self-care blood glucose monitors allow the user to tag the test result with an "event code" that can be used to organize the test results into categories. For example, a user might use a specific event code to identify test results obtained at a particular times of the day, a different

event code to identify a blood glucose reading obtained after a period of exercise, two additional event codes to identify blood glucose readings taken during hypoglycemia symptoms and hyperglycemia symptoms, etc. When event codes are provided and used, the event code typically is displayed with each recalled blood glucose test result.

Microprocessor-based blood glucose monitoring systems have advantages other than the capability of obtaining reliable blood glucose test results and storing a number of the results for later recall and review. By using low power microprocessor and memory circuits and powering the units with small, high capacity batteries (e.g., a single alkaline battery), extremely compact and light designs have been achieved that allow taking the blood glucose monitoring system to work, school, or anywhere else the user might go with people encountered by the user not becoming aware of the monitoring system. In addition, most microprocessor-based self-care blood glucose monitoring systems have a memory capacity that allows the system to be programmed by the manufacturer so that the monitor displays a sequence of instructions during any necessary calibration or system tests and during the blood glucose test sequence itself. In addition, the system monitors various system conditions during a blood glucose test (e.g., whether a test strip is properly inserted in the monitor and whether a sufficient amount of blood has been applied to the reagent impregnated portion of the strip) and if an error is detected generates an appropriate display (e.g., "retest"). A data port may be provided that allows test results stored in the memory of the microprocessor-based blood glucose monitoring system to be transferred to a data port (e.g., RS-232 connection) of a personal computer or other such device for subsequent analysis.

Microprocessor-based blood glucose monitoring systems are a significant advance over previously available self-care systems such as those requiring a diabetic to apply a blood sample to reagent activated portions of a test strip; wipe the blood sample from the

test strip after a predetermined period of time; and, after a second predetermined period of time, determine blood glucose level by comparing the color of the reagent activated regions of the test strip with a color chart supplied by the test strip manufacturer. However, several drawbacks and disadvantages exist, thus leaving several areas in which improvements would be of benefit both to the user and the healthcare professional. For example, establishing and maintaining diabetic healthcare often requires the diabetic to record additional data pertaining to medication, food intake, and exercise. However, the event codes of currently available microprocessor blood glucose monitoring systems do not allow the user of the system to tag and track blood glucose test results on a sufficiently accurate quantitative basis. For example, it would only be possible for the user to use the available event codes to classify stored blood glucose readings to indicate blood glucose tests taken immediately after a heavy meal and to identify blood glucose test results obtained after normal and light meals. This method of recording information not only requires subjective judgment by the system user, but will not suffice in a situation in which successfully controlling the user's diabetes requires the recording and tracking of relatively accurate information relating to food intake, exercise, or medication (e.g., insulin dosage). An otherwise significant advantage of currently available blood glucose monitoring systems is lost when blood glucose test results must be recorded and tracked with quantitative information relating to medication, food intake, or exercise. Specifically, the system user must record the required information along with a time and date tagged blood glucose test result by, for example, writing the information in a log book.

The use of event codes to establish subcategories of blood glucose test results has an additional disadvantage or drawback. In particular, although alphanumeric display devices are typically used in currently available microprocessor-based blood glucose

monitoring systems, the display units are limited to a single line of information having on the order of six characters. Moreover, since the systems include no provision for the user to enter alphanumeric information, any event codes that are used must be indicated on the display in a generic manner, e.g., displayed as "EVENT 1", "EVENT 2", etc. This limitation makes the system more difficult to use because the diabetic must either memorize his or her assignment of event codes or maintain a list that defines the event codes. The limited amount of data that can be displayed at any one time presents additional drawbacks and disadvantages. First, instructions and diagnostics that are displayed to the user when calibrating the system and using the system to obtain a blood glucose reading must be displayed a line at a time and in many cases, the information must be displayed in a cryptic manner. This limitation increases the likelihood that some potential users of the system (particularly children and the elderly) either will find the system complex to use or will not achieve the maximum benefit available from system use.

The above-discussed display limitations and other aspects of currently available blood glucose monitoring systems is disadvantageous in yet another way. Little statistical information can be made available to the user. For example, in diabetic healthcare maintenance, changes or fluctuations that occur in blood glucose levels during a day, a week, or longer period can provide valuable information to a diabetic and/or his or her healthcare professional. As previously mentioned, currently available systems do not allow associating blood glucose test results with attendant quantitative information relating to medication, food intake, or other factors such as exercise that affect a person's blood glucose level at any particular point in time. Thus, currently available blood glucose monitoring systems are not able to generate or display trend information that may be of significant value to a diabetic or the diabetic's healthcare professional.

The lack of provision for the entering of alphanumeric data also can be a disadvantage. For example, currently available blood glucose monitoring systems do not allow the user or the healthcare professional to enter information into the system such as medication dosage and other instructions or data that is relevant to the user's self-care health program.

The above-discussed disadvantages and drawbacks of currently available microprocessor-based blood glucose monitoring systems also have been impediments to adopting the basic technology of the system for other healthcare situations in which establishing and maintaining an effective regimen for cure or control is dependent upon (or at least facilitated by) periodically monitoring a condition and recording that condition along with time and date tags and other information necessary or helpful in establishing and maintaining a healthcare program.

Summary of the Invention

This invention provides a new and useful system for healthcare maintenance in which the invention serves as a peripheral device to a small handheld microprocessor-based unit of the type that includes a display screen, buttons or keys that allow a user to control the operation of the device and a program cartridge or other arrangement that can be inserted in the device to adapt the device to a particular application or function. The invention in effect converts the handheld microprocessor device into a healthcare monitoring system that has significant advantages over systems such as the currently available blood glucose monitoring systems. To perform this conversion, the invention includes a microprocessor-based healthcare data management unit, a program cartridge and a monitoring unit. When inserted in the handheld microprocessor unit, the program cartridge provides the software necessary to program the handheld microprocessor unit for operation with the microprocessor-based data management unit. Signal

communication between the data management unit and the handheld microprocessor unit is established by an interface cable. A second interface cable can be used to establish signal communication between the data management unit and the monitoring unit or, alternatively, the monitoring unit can be constructed as a plug-in unit having an electrical connector that mates with a connector mounted within a region that is configured for receiving the monitoring unit.

In operation, the control buttons or keys of the handheld microprocessor-based unit are used to select the operating mode for both the data management unit and the handheld microprocessor-based unit. In response to signals generated by the control buttons or keys, the data management unit generates signals that are coupled to the handheld microprocessor unit and, under control of the software contained in the program cartridge, establish an appropriate screen display on the handheld microprocessor-based unit display. In selecting system operating mode and other operations, the control buttons are used to position a cursor or other indicator in a manner that allows the system user to easily select a desired operating mode or function and provide any other required operator input. In the disclosed detailed embodiment of the invention several modes of operation are made available.

Brief Description of the Drawings

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1 is a block diagram that illustrates a healthcare monitoring system arranged in accordance with the invention;

FIGURE 2 diagrammatically illustrates monitoring systems constructed in accordance with the invention connected in signal communication with a remotely located computing facility which includes provision for making the data supplied by the monitoring system of the invention available to a designated healthcare professional and/or for providing data and instructions to the system user;

FIGURE 3 is a block diagram diagrammatically depicting the structural arrangement of the system data management unit and its interconnection with other components of the system shown in FIGURE 1; and

FIGURES 4-10 depict typical system screen displays of data and information that can be provided by the arrangements shown in FIGURES 1-3.

Detailed Description

FIGURE 1 depicts a self-care health monitoring system arranged in accordance with the invention. In the arrangement shown in FIGURE 1, a data management unit 10 is electrically interconnected with a handheld microprocessor-based unit 12 via a cable 14. Data management unit 10 also is electrically interconnected with a blood glucose monitor 16 of the type capable of sensing blood glucose level and producing an electrical signal representative thereof. Although FIGURE 1 illustrates blood glucose monitor 16 as being connected to data management unit 10 by a cable 18, it may be preferable to construct blood glucose monitor 16 as a plug-in unit that is placed in a recess or other suitable opening or slot in data management unit 10. Regardless of the manner in which blood glucose monitor 16 is interconnected with data management unit 10, both that interconnection and cable 14 are configured for serial data communication between the interconnected devices.

Also shown in FIGURE 1 are two additional monitoring devices 20 and 22, which are electrically connected for serial data communication with data management unit 10

via cables 24 and 26, respectively. Monitoring units 20 and 22 of FIGURE 1 represent devices other than blood glucose monitor 16 that can be used in the practice of the invention. For example, monitors can be provided for monitoring conditions such as blood pressure, pulse, and body temperature to thereby realize systems for self-care monitoring and control of conditions such as hypertension, certain heart conditions and various other afflictions and physical conditions. As is the case with blood glucose monitor 16, the additional monitors can be configured as plug-in units that are directly received by data management unit 10, or can be connected to data management unit 10 with cables (as shown in FIGURE 1).

As is shown in FIGURE 1, handheld microprocessor unit 12 includes a display screen 28 and a plurality of switches or keys (30, 32, 34, 36, and 38 in FIGURE 1), which are mounted on a small housing 40. Located in the interior of housing 40, but not shown in FIGURE 1, are a microprocessor, memory circuits, and circuitry that interfaces switches 30, 32, 34, 36 and 38 with the microprocessor. Stored in the memory of program handheld microprocessor unit 12 is a set of program instructions that establishes a data protocol that allows handheld microprocessor unit 12 to perform digital data signal processing and generate desired data or graphics for display on display unit 28 when a program cartridge 42 is inserted in a slot or other receptacle in housing 40. That is, program cartridge 42 includes read-only memory units (or other memory means such as battery-powered random access memory) which stores program instructions and data. When combined with program instructions and data included in the internal memory circuits of handheld microprocessor unit 12, the instructions and data of program cartridge 42 cause handheld microprocessor unit 12 to be programmed for a particular purpose or use. As is known in the art, the program instructions and data stored in the internal memory of handheld microprocessor-based unit 12 can be configured and

arranged so that different program cartridges configure handheld microprocessor unit 12 for different applications or purposes. In each such purpose or application, the plurality of switches or keys (30, 32, 34, 36, and 38 in FIGURE 1) are selectively operated to provide signals that result in pictorial and/or printed information being displayed by display unit 42.

Various devices are known that meet the above-set forth description of handheld microprocessor unit 12. For example, compact devices are available in which the plurality of keys allows alphanumeric entry and internal memory is provided for storing information such as names, addresses, phone numbers, and an appointment calendar. Small program cartridges or cards can be inserted in these devices to program the device for various purposes such as the playing of games, spreadsheet application, and foreign language translation sufficient for use in travel. More recently, less compact products that have more extensive computational capability and are generally called "palm top computers" have been introduced into the marketplace. These devices also can include provision for programming the device by means of an insertable program card or cartridge.

The currently preferred embodiments of the invention are configured and arranged to operate in conjunction with yet another type of handheld microprocessor unit. Specifically, in the currently preferred embodiments of the invention, program cartridge 42 is electrically and physically compatible with commercially available compact video game systems, such as the system manufactured by Nintendo of America Inc. under the trademark "GAME BOY." Configuring data management unit 10 and program cartridge 42 for operation with a handheld video game system has several advantages. For example, the display unit of such a device provides display resolution that allows the invention to display both multi-line alphanumeric information and graphical data. In this

regard, the 160 x 144 pixel dot matrix-type liquid crystal display screen currently used in the above-referenced compact video game systems provides sufficient resolution for at least six lines of alphanumeric text, as well as allowing graphical representation of statistical data such as graphical representation of blood glucose test results for a day, a week, or longer.

Another advantage of realizing handheld microprocessor unit 12 in the form of a compact video game system is the relatively simple, yet versatile arrangement of switches that is provided by such a device. For example, as is indicated in FIGURE 1, a compact video game system includes a control pad 30 that allows an object displayed on display unit 42 to be moved in a selected direction (i.e., up-down or left-right). As also is indicated in FIGURE 1, compact video game systems typically provide two pair of distinctly-shaped push button switches. In the arrangement shown in FIGURE 1, a pair of spaced-apart circular push button switches (36 and 38) and a pair of elongate switches (32 and 34) are provided. The functions performed by the two pairs of switches is dependent upon the program instructions contained in each program cartridge 42.

Yet another advantage of utilizing a compact video game system for handheld microprocessor based unit 12 of FIGURE 1 is the widespread popularity and low cost of such units. In this regard, manufacture and sale of a data management unit 10, blood glucose monitor 16 and program cartridge 42 that operate in conjunction with a compact microprocessor based video allows the self-care health monitoring system of FIGURE 1 to be manufactured and sold at a lower cost than could be realized in an arrangement in which handheld unit 12 is designed and manufactured solely for use in the system of FIGURE 1.

An even further advantage of using a compact video game system for handheld microprocessor 12 is that such video game systems include means for easily establishing

the electrical interconnection provided by cable 14 in FIGURE 1. In particular, such compact video game systems include a connector mounted to the game unit housing (40 in FIGURE 1) and a cable that can be connected between the connectors of two video game units to allow interactive operation of the two interconnected units (i.e., to allow contemporaneous game play by two players or competition between players as they individually play identical but separate games). In the preferred embodiments of the invention, the "two-player" cable supplied with the compact video game unit being used as handheld microprocessor unit 12 is used as cable 14 to establish serial data communication between the handheld microprocessor unit 12 (compact video game system) and data management unit 10. In these preferred embodiments, the program instructions stored on the memory of data management unit 10 and program cartridge 42 respectively program data management unit 10 and the compact video game system (i.e., handheld microprocessor unit 12) for interactive operation in which switches 30, 32, 34, 36 and 38 are used to control the operation of data management unit 10 (e.g., to select a particular operational mode such as performance of a blood glucose test or the display of statistical test data and, in addition, to control operation such as selection of an option during operation of the system in a particular operational mode). In each operational mode, data management unit 10 processes data in accordance with program instructions stored in the memory circuits of data management unit 10. Depending upon the operational mode selected by the user, data is supplied to data management unit 10 by blood glucose monitor 16, by additional monitors (20 and 22 in FIGURE 1) or any interconnected computers (hereinafter described as elements 48 and 54 in FIGURE 1) During operational mode, switches 30, 32, 34, 36 and 38 are selectively activated so that signals are selectively coupled to the video game system (handheld microprocessor unit 12) and processed in accordance with program instructions stored in program

cartridge 42. The signal processing performed by handheld microprocessor unit 12 results in the display of alphanumeric, symbolic, or graphic information on the video game display screen (i.e., display unit 28 in FIGURE 1) which allow the user to control system operation and obtain desired test results and other information.

With continued reference to FIGURE 1, data management unit 10 of the currently preferred embodiments of the invention includes a data port 44 that allows communication between data management unit 10 and a personal computer 48 (or other programmable data processor). In the currently preferred embodiments of the invention, data port 44 is an RS-232 connection that allows serial data communication between data management unit 10 and personal computer 48. In the practice of the invention, personal computer 48 can be used to supplement data management unit 10 by, for example, performing relatively complex or sophisticated analyses of blood glucose and other data that has been supplied to and stored in the memory circuits of data management unit 10. Alternatively, personal computer 48 can be used to supply data to data management unit 10 that is not conveniently supplied by using handheld microprocessor switches 30, 32, 34, 36 and 38 as an operator interface to the system shown in FIGURE 1. For example, some embodiments of the invention may employ a substantial amount of alphanumeric information that must be entered by the system user. Although it is possible to enter such data by using switches 30, 32, 34, 36 and 38 in conjunction with menus and selection screens displayed on display screen 28 of FIGURE 1, it may be more advantageous to use a device such as personal computer 48 for entry of such data. However, if personal computer 48 is used in this manner, some trade-off of system features may be required because data management unit 10 must be temporarily interconnected with personal computer 48 during these operations. That is, some loss of

system mobility might result because a suitably programmed personal computer would be needed at each location at which data entry or analysis is to occur.

As is indicated in FIGURE 1, data management unit 10 of the currently preferred embodiments of the invention also includes a modem that allows data communication between data management unit 10 and a remote computing facility 54 via a conventional telephone line (indicated by reference numeral 50 in FIGURE 1) and a modem 52 that interconnects remote computing facility 54 and telephone line 50. As shall be described in more detail, remote computing facility 54 facilitates communication between a user of the system shown in FIGURE 1 and his or her healthcare professional and can provide additional services such as updating system software.

Regardless of whether a compact video game system, another type of commercially available handheld microprocessor-based unit, or a specially designed unit is used, the preferred embodiments of FIGURE 1 provide a self-care blood glucose monitoring system in which program cartridge 42: (a) adapts handheld microprocessor unit 12 for displaying instructions for performing the blood glucose test sequence and associated calibration and test procedures; (b) adapts handheld microprocessor unit 12 for displaying (graphically or alphanumerically) statistical data such as blood glucose test results taken during a specific period of time (e.g., a day, week, etc.); (c) adapts handheld microprocessor unit 12 for supplying control signals and signals representative of food intake or other useful information to data management unit 10; (d) adapts handheld microprocessor unit 12 for simultaneous graphical display of blood glucose levels with information such as food intake; and, (e) adapts handheld microprocessor unit 12 for displaying information or instructions from a healthcare professional that are coupled to data management unit 10 from a remote computing facility 54. The manner in which the

arrangement of FIGURE 1 implements the above-mentioned functions and others can be better understood with reference to FIGURES 2 and 3.

Referring first to FIGURE 2, in relatively large scale application of the invention, remote computing facility 54 of FIGURE 1 functions as a clearinghouse (i.e., central server) that is identified by reference numeral 56 in FIGURE 2. Clearinghouse 56 receives data from a plurality of self-care microprocessor-based healthcare systems of the type shown in FIGURE 1, with the individual self-care health monitoring systems being indicated in FIGURE 2 by reference numeral 58. Preferably, the data supplied to clearinghouse 56 by each individual self-care health monitoring system 58 consists of "raw data," i.e., test results and related data that was stored in memory circuits of data management unit 10, without further processing by data management unit 10. For example, with respect to the arrangement shown in FIGURE 1, blood glucose test results and associated data such as food intake information, medication dosage and other such conditions are transmitted to clearinghouse 56 and stored with a digitally encoded signal that identifies both the source of the information (i.e., the system user or patient) and those having access to the stored information (i.e., the system user's doctor or other healthcare professional).

In FIGURE 2, rectangular outline 60 represents one of numerous remotely located healthcare professionals who can utilize clearinghouse 56 and the arrangement described relative to FIGURE 1 in monitoring and controlling patient healthcare programs. Shown within outline 60 is a computer 62 (e.g., personal computer), which is coupled to clearinghouse 56 by means of a modem (not shown in FIGURE 2) and a telephone line 64. The arrangement of FIGURE 2 also diagrammatically indicates a facsimile machine ("fax"), which is coupled to clearinghouse 56 by means of a second

device such as a mouse), the healthcare professional can establish data communication between computer 62 and clearinghouse 56 via telephone line 64. Once data communication is established between computer 62 and clearinghouse 56, patient information can be obtained from clearinghouse 56 in a manner similar to the manner in which subscribers to various database services access and obtain information. In particular, the healthcare professional can transmit an authorization code to clearinghouse 56 that identifies the healthcare professional as an authorized user of the clearinghouse and, in addition, can transmit a signal representing the patient for which healthcare information is being sought. As is the case with conventional database services and other arrangements, the identifying data is keyed into computer 62 by means of a conventional keyboard (not shown in FIGURE 2) in response to prompts that are generated at clearinghouse 56 for display by the display unit of computer 62 (not shown in FIGURE 2).

Depending upon the hardware and software arrangement of clearinghouse 56 and selections made by the healthcare professional via computer 62, patient information can be provided to the healthcare professional in different ways. For example, computer 62 can be operated to access data in the form that it is stored in the memory circuits of clearinghouse 56 (i.e., raw data that has not been processed or altered by the computational or data processing arrangements of clearinghouse 56). Such data can be processed, analyzed, printed and/or displayed by computer 62 using commercially available or custom software. On the other hand, various types of analyses may be performed by clearinghouse 56 with the results of the analyses being transmitted to the remotely located healthcare professional 60. For example, clearinghouse 56 can process and analyze data in a manner identical to the processing and analysis provided by the self-care monitoring system of FIGURE 1. With respect to such processing and any other

analysis and processing provided by clearinghouse 56, results expressed in alphanumeric format can be sent to computer 62 via telephone line 64 and the modem associated with computer 62, with conventional techniques being used for displaying and/or printing the alphanumeric material for subsequent reference. In addition, the arrangement of FIGURE 2 allows analytical or statistical results to be transmitted to remotely located healthcare professional 60 via telephone line 68 and facsimile machine 66. For example, data supplied by the arrangement can be processed by clearinghouse 56 using conventional data processing techniques to obtain a collection of data or statistical information that lends itself to presentation in a pictorial or graphic format. In such a case, the data can be converted by clearinghouse 56 to a conventional facsimile transmission format, which can be sent to the healthcare professional's facsimile machine 66 upon request of the healthcare professional (i.e., communication via computer 62).

The arrangement of FIGURE 2 also allows the healthcare professional to send messages and/or instructions to each patient via computer 62, telephone line 64, and clearinghouse 56. In particular, clearinghouse 56 can be programmed to generate a menu that is displayed by computer 62 and allows the healthcare professional to select a mode of operation in which information is to be sent to clearinghouse 56 for subsequent transmission to a user of the system described relative to FIGURE 1. This same menu (or related submenus) can be used by the healthcare professional to select one or more modes of operation of the above-described type in which either unmodified patient data or the results of data that has been analyzed by clearinghouse 56 is provided to the healthcare provider via computer 62 and/or facsimile machine 66.

In the currently contemplated arrangements, operation of the arrangement of FIGURE 2 to provide the user of the invention with messages or instructions such as

changes in medication or other aspects of the healthcare program is similar to the operation that allows the healthcare professional to access data sent by a patient, i.e., transmitted to clearinghouse 56 by a data management unit 10 of FIGURE 1. The process differs in that the healthcare professional enters the desired message or instruction via the keyboard or other interface unit of computer 62. Once the data is entered and transmitted to clearinghouse 56, it is stored for subsequent transmission to the user for whom the information or instruction is intended.

With respect to transmitting stored messages or instructions to a user of the invention, at least two techniques are available. The first technique is based upon the manner in which operational modes are selected in the practice of the invention. Specifically, in the currently preferred embodiments of the invention, program instructions that are stored in data management unit 10 and program cartridge 42 cause the system of FIGURE 1 to generate menu screens which are displayed by display unit 28 of handheld microprocessor unit 12. The menu screens allow the system user to select the basic mode in which the system of FIGURE 1 is to operate and, in addition, allow the user to select operational subcategories within the selected mode of operation. Various techniques are known to those skilled in the art for displaying and selecting menu items. For example, in the practice of this invention, one or more main menus can be generated and displayed which allow the system user to select operational modes that may include: (a) a monitor mode (e.g., monitoring of blood glucose level); (b) a display mode (e.g., displaying previously obtained blood glucose test results or other relevant information); (c) an input mode (e.g., a mode for entering data such as providing information that relates to the healthcare regimen, medication dosage, food intake, etc., and (d) a communications mode (for establishing a communication link between data management

unit 10 and personal computer 48 of FIGURE 1; or between data management Unit 10 and a remote computing facility such as clearinghouse 56 of FIGURE 2).

In embodiments of the invention that employ a compact video game system for handheld microprocessor unit 12, the selection of menu screens and the selection of menu screen items preferably is accomplished in substantially the same manner as menu screens and menu items are selected during the playing of a video game. For example, the program instructions stored in data management unit 10 and program cartridge 42 of the arrangement of FIGURE 1 can be established so that a predetermined one of the compact video game switches (e.g., switch 32 in FIGURE 1) allows the system user to select a desired main menu in the event that multiple main menus are employed. When the desired main menu is displayed, operation by the user of control pad 30 allows a cursor or other indicator that is displayed on the menu to be positioned adjacent to or over the menu item to be selected. Activation of a switch (e.g., switch 36 of the depicted handheld microprocessor unit 12) causes the handheld microprocessor unit 12 and/or data management unit 10 to initiate the selected operational mode or, if selection of operational submodes is required, causes handheld microprocessor unit 12 to display a submenu.

In view of the above-described manner in which menus and submenus are selected and displayed, it can be recognized that the arrangement of FIGURE 1 can be configured and arranged to display a menu or submenu item that allows the user to obtain and display messages or instructions that have been provided by a healthcare professional and stored in clearinghouse 56. For example, a submenu that is generated upon selection of the previously mentioned communications mode can include submenu items that allow the user to select various communication modes, including a mode in which serial data communication is established between data management unit 10 and clearinghouse 56 and

data management unit 10 transmits a message status request to clearinghouse 56. When this technique is used, the data processing system of clearinghouse 56 is programmed to search the clearinghouse memory to determine whether a message exists for the user making the request. Any messages stored in memory for that user are then transmitted to the user and processed for display on display unit 28 of handheld microprocessor unit 12. If no messages exist, clearinghouse 56 transmits a signal that causes display unit 28 to indicate "no messages." In this arrangement, clearinghouse 56 preferably is programmed to store a signal indicating that a stored message has been transmitted to the intended recipient (user). Storing such a signal allows the healthcare professional to determine that messages sent to clearinghouse 56 for forwarding to a patient have been transmitted to that patient. In addition, the program instructions stored in data management unit 10 of FIGURE 1 preferably allow the system user to designate whether received messages and instructions are to be stored in the memory of data management unit 10 for subsequent retrieval or review. In addition, in some instances it may be desirable to program clearinghouse 56 and data management unit 10 so that the healthcare professional can designate (i.e., flag) information such as changes in medication that will be prominently displayed to the user (e.g., accompanied by a blinking indicator) and stored in the memory of data management unit 10 regardless of whether the system user designates the information for storage.

A second technique that can be used for forwarding messages or instructions to a user does not require the system user to select a menu item requesting transmission by clearinghouse 56 of messages that have been stored for forwarding to that user. In particular, clearinghouse 56 can be programmed to operate in a manner that either automatically transmits stored messages for that user when the user operates the system of FIGURE 1 to send information to the clearinghouse or programmed to operate in a

manner that informs the user that messages are available and allows the user to access the messages when he or she chooses to do so.

FIGURE 3 illustrates the manner in which data management unit 10 is arranged and interconnected with other system components for effecting the above-described operational aspects of the invention and additional aspects that are described relative to FIGURES 4-10. As is symbolically indicated in FIGURE 3, handheld microprocessor unit 12 and blood glucose monitor 16 are connected to a dual universal asynchronous receiver transmitter 70 (e.g., by cables 14 and 18 of FIGURE 1, respectively). As also is indicated in FIGURE 3 when a personal computer 48 (or other programmable digital signal processor) is connected to data port 44 signal communication is established between personal computer 48 and a second dual universal asynchronous receiver transmitter 72, which is included in data management unit 10. Additionally, dual universal asynchronous receiver transmitter 72 is coupled to modem 46 so that data communication can be established between data management unit 10 and a remote computing facility 54 (e.g., clearinghouse 56 of FIGURE 2).

Currently preferred embodiments of data management unit 10 include a plurality of signal sensors 74, with an individual signal sensor being associated with each device that is (or may be) interconnected with data management unit 10. As previously discussed and as is indicated in FIGURE 3, these devices include handheld microprocessor unit 12, blood glucose monitor 16, personal computer 48, and remote computing facility 54. Each signal sensor 74 that is included in data management unit 10 is electrically connected for receiving a signal that will be present when the device with which that particular signal sensor is associated is connected to data management unit 10 and, in addition, is energized (e.g., turned on). For example, in previously mentioned embodiments of the invention in which data port 44 is an RS-232 connection, the signal

sensor 74 that is associated with personal computer 48 can be connected to an RS-232 terminal that is supplied power when a personal computer is connected to data port 44 and the personal computer is turned on. In a similar manner, the signal sensor 74 that is associated with remote computing facility 54 can be connected to modem 46 so that the signal sensor 74 receives an electrical signal when modem 46 is interconnected to a remote computing facility (e.g., clearinghouse 56 of FIGURE 2) via a telephone line 50.

In the arrangement of FIGURE 3, each signal sensor 74 is a low power switch circuit (e.g., a metal-oxide semiconductor field-effect transistor circuit), which automatically energizes data management unit 10 whenever one or more of the devices associated with signal sensors 74 are connected to data management unit 10 and are energized. Thus, as is indicated in FIGURE 3 by signal path 76, each signal sensor 74 is interconnected with power supply 78, which supplies operating current to the circuitry of data management unit 10 and typically consists of one or more small batteries (e.g., three AAA alkaline cells).

The microprocessor and other conventional circuitry that enables data management unit 10 to process system signals in accordance with stored program instructions is indicated in FIGURE 3 by central processing unit (CPU) 80. As is indicated in FIGURE 3 by interconnection 82 between CPU 80 and battery 78, CPU 80 receives operating current from power supply 78, with power being provided only when one or more of the signal sensors 74 are activated in the previously described manner. A clock/calendar circuit 84 is connected to CPU 80 (via signal path 86 in FIGURE 3) to allow time and date tagging of blood glucose tests and other information. Although not specifically shown in FIGURE 3, operating power is supplied to clock/calendar 84 at all times.

In operation, CPU 80 receives and sends signals via a data bus (indicated by signal path 88 in FIGURE 3) which interconnects CPU 80 with dual universal asynchronous receiver transmitters 70 and 72. The data bus 88 also interconnects CPU 80 with memory circuits which, in the depicted embodiment, include a system read-only memory (ROM) 90, a program random access memory (RAM) 92, and an electronically erasable read-only memory (EEROM) 94. System ROM 90 stores program instructions and any data required in order to program data management unit 10 so that data management unit 10 and a handheld microprocessor unit 12 that is programmed with a suitable program cartridge 72 provide the previously discussed system operation and system operation that will be described relative to FIGURES 4-10. During operation of the system, program RAM 92 provides memory space that allows CPU 80 to carry out various operations that are required for sequencing and controlling the operation of the system of FIGURE 1. In addition, RAM 92 can provide memory space that allows external programs (e.g., programs provided by clearinghouse 56) to be stored and executed. EEROM 94 allows blood glucose test results and other data information to be stored and preserved until the information is no longer needed (i.e., until purposely erased by operating the system to provide an appropriate erase signal to EEROM 94).

FIGURES 4-10 illustrate typical screen displays that are generated by the arrangement of the invention described relative to FIGURES 1-3. Reference will first be made to FIGURES 4 and 5, which exemplify screen displays that are associated with operation of the invention in the blood glucose monitoring mode. Specifically, in the currently preferred embodiments of the invention, blood glucose monitor 16 operates in conjunction with data management unit 10 and handheld microprocessor unit 12 to: (a) perform a test or calibration sequence in which tests are performed to confirm that the system is operating properly; and, (b) perform the blood glucose test sequence in which

blood glucose meter 16 senses the user's blood glucose level. Suitable calibration procedures for blood glucose monitors are known in the art. For example, blood glucose monitors often are supplied with a "code strip," that is inserted in the monitor and results in a predetermined value being displayed and stored in memory at the conclusion of the code strip calibration procedure. When such a code strip calibration procedure is used in the practice of the invention, the procedure is selected from one of the system menus. For example, if the system main menu includes a "monitor" menu item, a submenu displaying system calibration options and an option for initiating the blood glucose test may be displayed when the monitor menu item is selected. When a code strip option is available and selected, a sequence of instructions is generated and displayed by display screen 28 of handheld microprocessor unit 12 to prompt the user to insert the code strip and perform all other required operations. At the conclusion of the code strip calibration sequence, display unit 28 of handheld microprocessor unit 12 displays a message indicating whether or not the calibration procedure has been successfully completed. For example, FIGURE 4 illustrates a screen display that informs the system user that the calibration procedure was not successful and that the code strip should be inserted again (i.e., the calibration procedure is to be repeated). As is indicated in FIGURE 4, display screens that indicate a potential malfunction of the system include a prominent message such as the "Attention" notation included in the screen display of FIGURE 4.

As previously indicated, the blood glucose test sequence that is employed in the currently preferred embodiment of the invention is of the type in which a test strip is inserted in a receptacle that is formed in the blood glucose monitor. A drop of the user's blood is then applied to the test strip and a blood glucose sensing sequence is initiated. When the blood glucose sensing sequence is complete, the user's blood glucose level is displayed.

In the practice of the invention, program instructions stored in data management unit 10 (e.g., system ROM 90 of FIGURE 3) and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 cause the system to display step-by-step monitoring instructions to the system user and, in addition, preferably result in display of diagnostic messages if the test sequence does not proceed in a normal fashion. Although currently available self-contained microprocessor base blood glucose monitors also display test instruction and diagnostic messages, the invention provides greater message capacity and allows multi-line instructions and diagnostic messages that are displayed in easily understood language rather than cryptic error codes and abbreviated phraseology that is displayed one line at a time. For example, as is shown in FIGURE 5, the complete results of a blood glucose test (date, time of day, and blood glucose level in milligrams per deciliter) can be concurrently displayed by display screen 28 of handheld microprocessor unit 12 along with an instruction to remove the test strip from blood glucose monitor 16. As previously mentioned, when the blood glucose test is complete, the time and date tagged blood glucose test result is stored in the memory circuits of data management unit 10 (e.g., stored in EEPROM 94 of FIGURE 3).

The arrangement shown and described relative to FIGURES 1-3 also is advantageous in that data relating to food intake, concurrent medication dosage and other conditions easily can be entered into the system and stored with the time and date tagged blood glucose test result for later review and analysis by the user and/or his or her healthcare professional. Specifically, a menu generated by the system at the beginning or end of the blood glucose monitoring sequence can include items such as "hypoglycemic" and "hyperglycemic," which can be selected using the switches of handheld microprocessor unit 12 (e.g., operation of control pad 30 and switch 36 in FIGURE 1) to indicate the user was experiencing hypoglycemic or hyperglycemic symptoms at the time

of monitoring blood glucose level. Food intake can be entered in terms of "Bread Exchange" units or other suitable terms by selecting a "food intake menu item and using a submenu display and the switches of handheld microprocessor 12 to select and enter the appropriate information. A similar menu item - submenu selection process also can be used to enter medication data such as the type of insulin used at the time of the glucose monitoring sequence and the dosage.

As was previously mentioned, program instructions stored in data management unit 10 and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 enable the system to display statistical and trend information either in a graphic or alphanumeric format. As is the case relative to controlling other operational aspects of the system, menu screens are provided that allow the system user to select the information that is to be displayed. For example, in the previously discussed embodiments in which a system menu includes a "display" menu item, selection of the menu item results in the display of one or more submenus that list available display options. For example, in the currently preferred embodiments, the user can select graphic display of blood glucose test results over a specific period of time, such as one day, or a particular week. Such selection results in displays of the type shown in FIGURES 6 and 7, respectively. When blood glucose test results for a single day are displayed (FIGURE 6), the day of the week and date can be displayed along with a graphic representation of changes in blood glucose level between the times at which test results were obtained. In the display of FIGURE 6, small icons identify points on the graphic representation that correspond to the blood glucose test results (actual samples). Although not shown in FIGURE 6, coordinate values for blood glucose level and time of day can be displayed if desired. When the user chooses to display a weekly trend graph (FIGURE 7), the display generated by the system is similar to the display of a daily graph,

having the time period displayed in conjunction with a graph that consists of lines interconnecting points that correspond to the blood glucose test results.

The screen display shown in FIGURE 8 is representative of statistical data that can be determined by the system of FIGURE 1 (using conventional computation techniques) and displayed in alphanumeric format. More specifically, the exemplary screen display of FIGURE 8 provides statistical data for blood glucose levels over a period of time (e.g., one week) or, alternatively, for a specified number of monitoring tests. In the exemplary display of FIGURE 8, the system calculates and displays the average blood glucose level and the standard deviation. Displayed also is the number of blood glucose test results that were analyzed to obtain the average and the standard deviation; the number of test results under a predetermined level (50 milligrams per deciliter in the screen display shown in FIGURE 8); and the number of blood glucose tests that were conducted while the user was experiencing hypoglycemic symptoms. As previously noted, in the preferred embodiments of the invention, a screen display that is generated during the blood glucose monitoring sequence allows the user to identify the blood sample being tested as one taken while experiencing hyperglycemic or hypoglycemic symptoms and, in addition, allows the user to specify other relevant information such as food intake and medication information.

The currently preferred embodiments of the invention also allow the user to select a display menu item that enables the user to sequentially address, in chronological order, the record of each blood glucose test. As is indicated in FIGURE 9, each record presented to the system user includes the data and time at which the test was conducted, the blood glucose level, and any other information that the user provided. For example, the screen display of FIGURE 9 indicates that the user employed handheld microprocessor unit 12 as an interface to enter data indicating use of 12.5 units of regular

insulin; 13.2 units of "NPH" insulin; food intake of one bread exchange unit; and pre-meal hypoglycemic symptoms.

Use of data management unit 10 in conjunction with handheld microprocessor unit 12 also allows display of blood glucose test results along with food intake and/or medication information. For example, shown in FIGURE 10 is a daily graph in which blood glucose level is displayed in the manner described relative to FIGURE 6. Related food intake and medication dosage is indicated directly below contemporaneous blood glucose levels by vertical bar graphs.

It will be recognized by those skilled in the art that the above-described screen displays and system operation can readily be attained with conventional programming techniques of the type typically used in programming microprocessor arrangements. It also will be recognized by those skilled in the art that various other types of screen displays can be generated and, in addition, that numerous other changes can be made in the embodiments described herein without departing from the scope and the spirit of the invention.

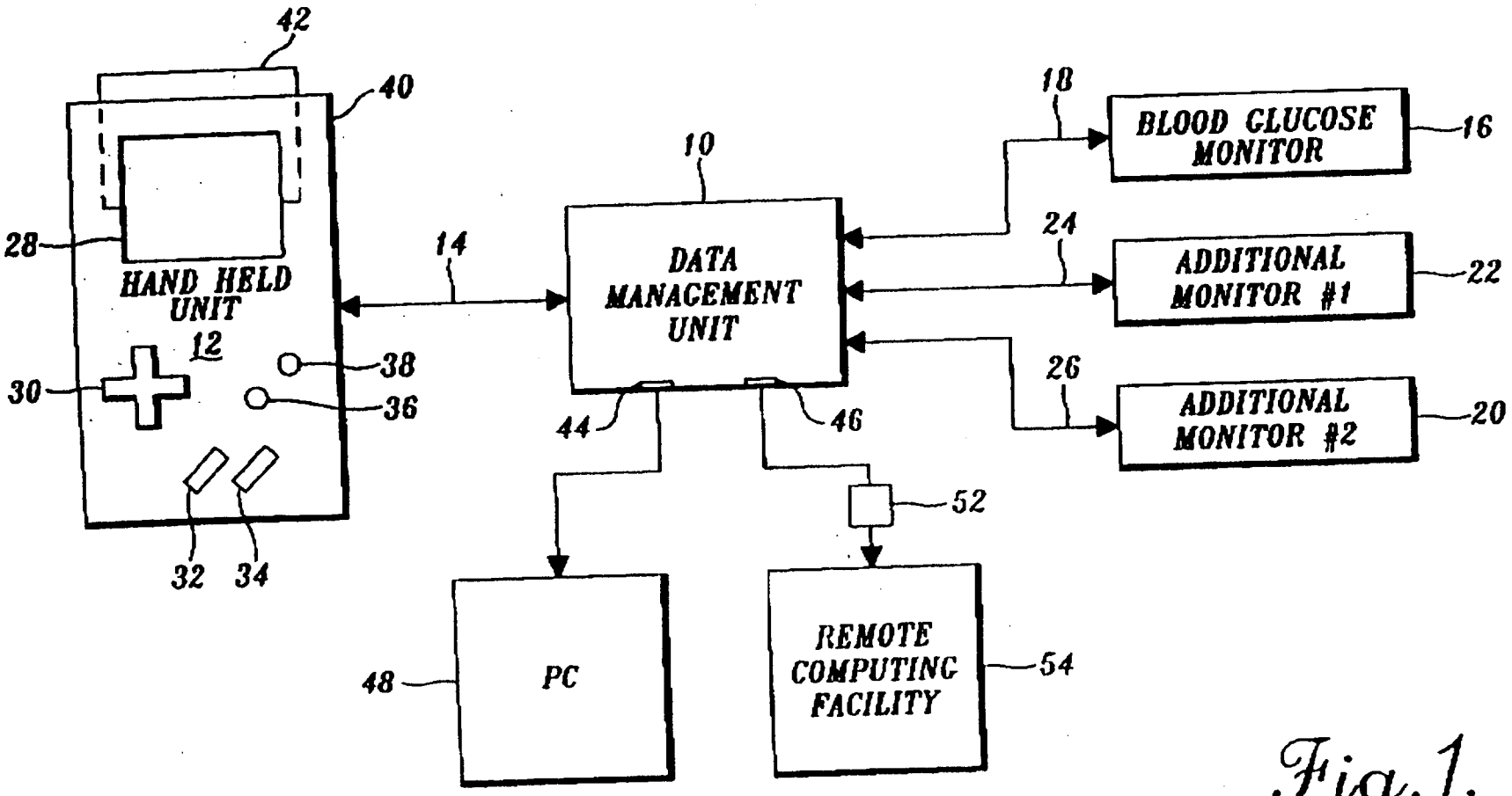
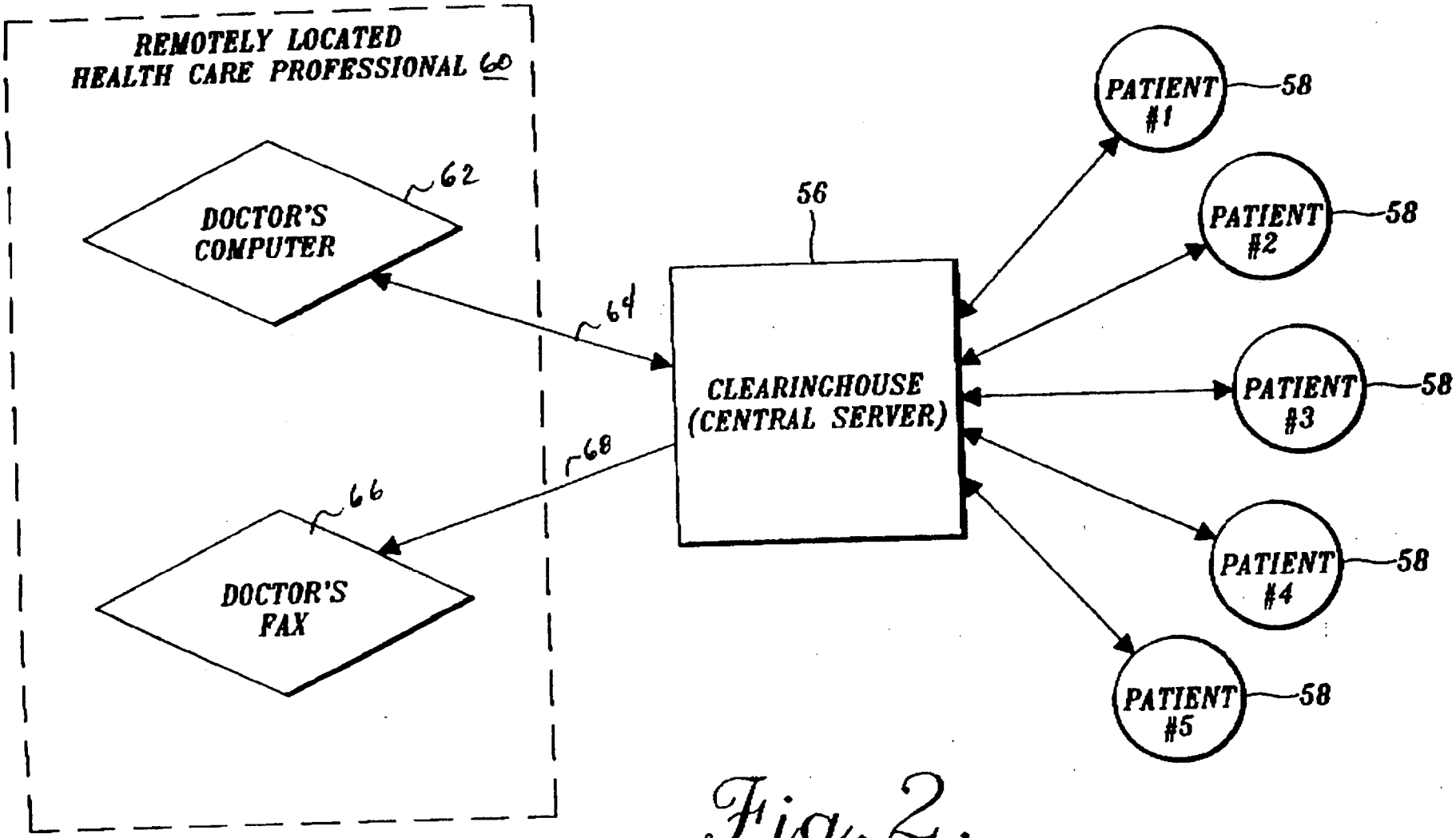

42
40
28
HAND HELD UNIT
12
30
38
36
32
34
14
10
DATA MANAGEMENT UNIT
44
46
18
BLOOD GLUCOSE MONITOR
16
24
ADDITIONAL MONITOR #1
22
26
ADDITIONAL MONITOR #2
20
52
48
PC
REMOTE COMPUTING FACILITY
54

Fig. 1.


REMOTELY LOCATED
HEALTH CARE PROFESSIONAL 60
DOCTOR'S
COMPUTER
62
64
DOCTOR'S
FAX
66
68
56
CLEARINGHOUSE
(CENTRAL SERVER)
PATIENT
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#2
58
PATIENT
#3
58
PATIENT
#4
58
PATIENT
#5
58

Fig. 2.

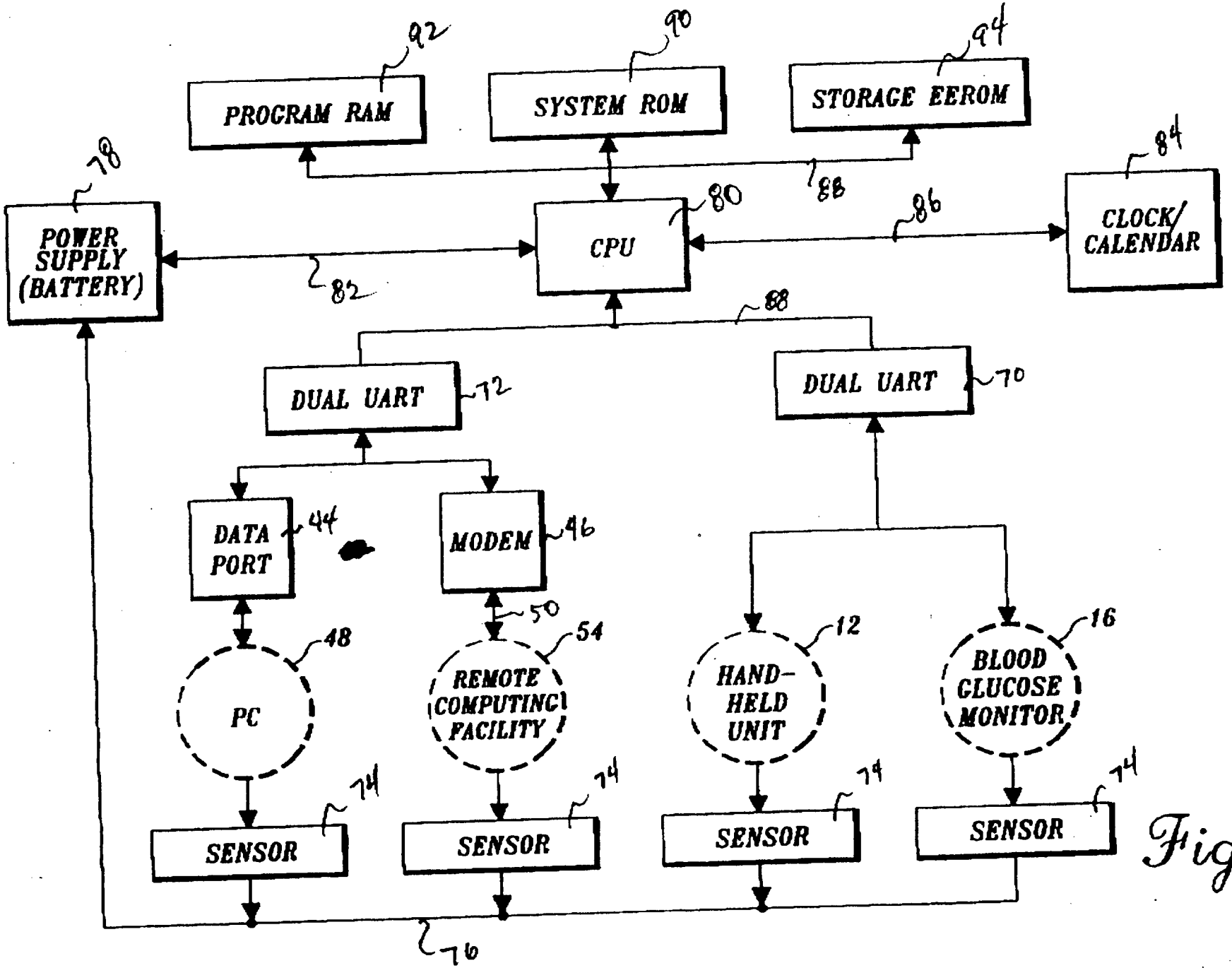

92
PROGRAM RAM
90
SYSTEM ROM
94
STORAGE EEROM
78
POWER SUPPLY (BATTERY)
88
84
CLOCK/ CALENDAR
80
CPU
86
82
88
DUAL UART
72
DUAL UART
70
DATA PORT
44
MODEM
46
50
48
54
12
16
PC
REMOTE COMPUTING FACILITY
HAND-HELD UNIT
BLOOD GLUCOSE MONITOR
74
74
74
74
SENSOR
SENSOR
SENSOR
SENSOR
76

Fig. 3.

Fig.4.

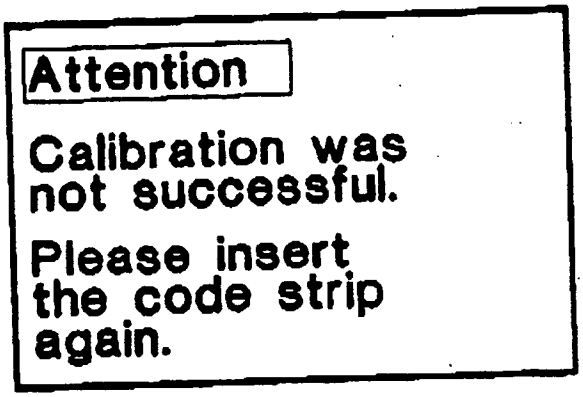


Fig.5.

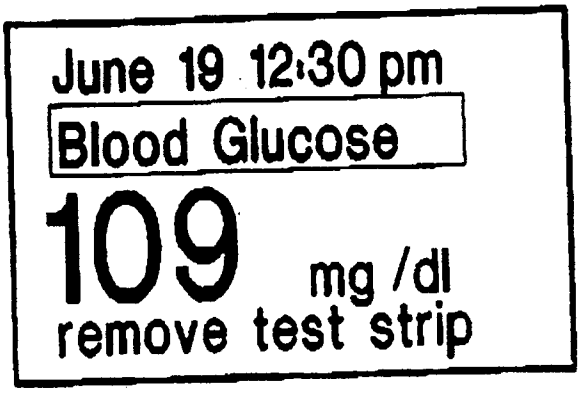


Fig.6.

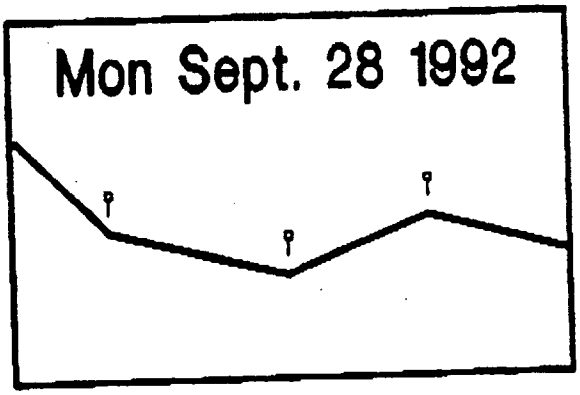


Fig.7.

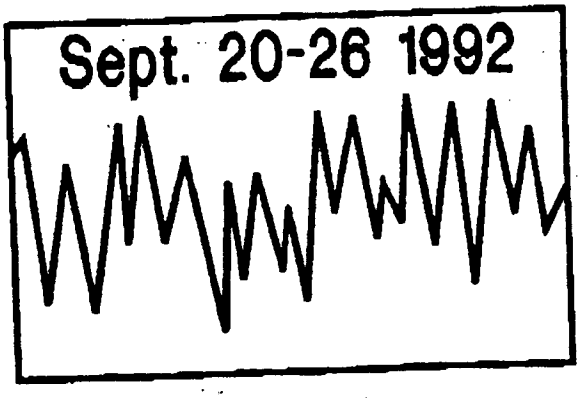


Fig. 8.

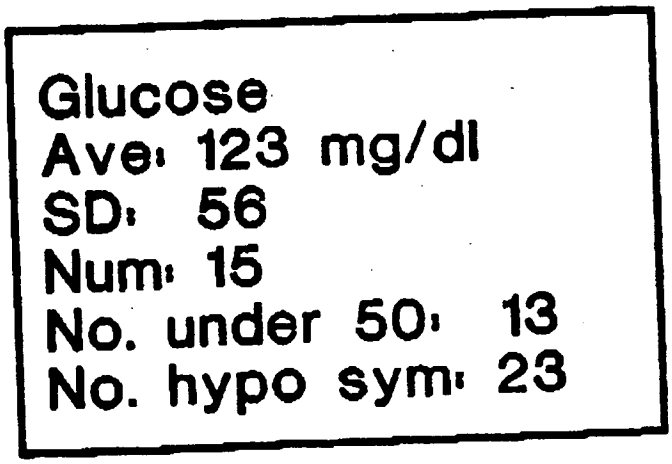


Fig. 9.

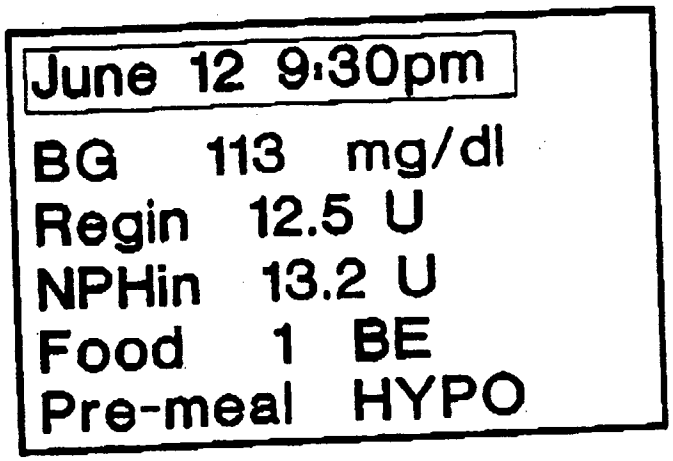


Fig. 10.

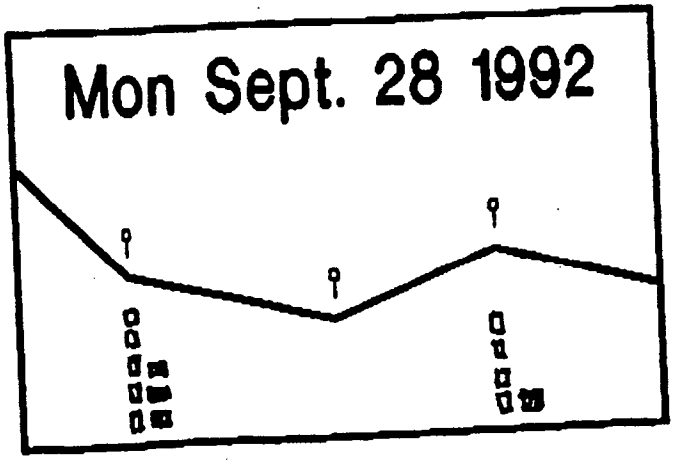


Exhibit 9

Facsimile Cover Sheet

To: Mr. James Anable Esq.
Company: Christiansen O'Connor
Phone: (206) 682-8100
Fax: (206) 224-0779

From: Steve Brown
Company: Raya Systems, Inc
Phone: (415) 949-3933
Fax: (415) 949-3935

Healthboy

Date: 10/02/92
Pages including this cover page: 3

Comments:

******* PANAFAX 155 *** -JOURNAL- ********** DATE 01/17/1900 ***** TIME 16:07 *********

NO.	COM	DOC	DURATION	X/R	IDENTIFICATION	DATE	TIME	DIAGNOSTIC
28	OK	03	00:01'35	XMT	GROUP3	01/17	16:05	020440AC0800

********** -PANASONIC- ********** - ********

October 2, 1992

Mr. James Anable Esq.
Christiansen O'Connor
2800 Pacific First Center
1420 Fifth Avenue
Seattle, WA 98101

Dear James:

I am faxing you the diagram which shows the basic system. I am worried about focusing on the particulars and losing the fundamentals, and I think this diagram needs to be in the application.

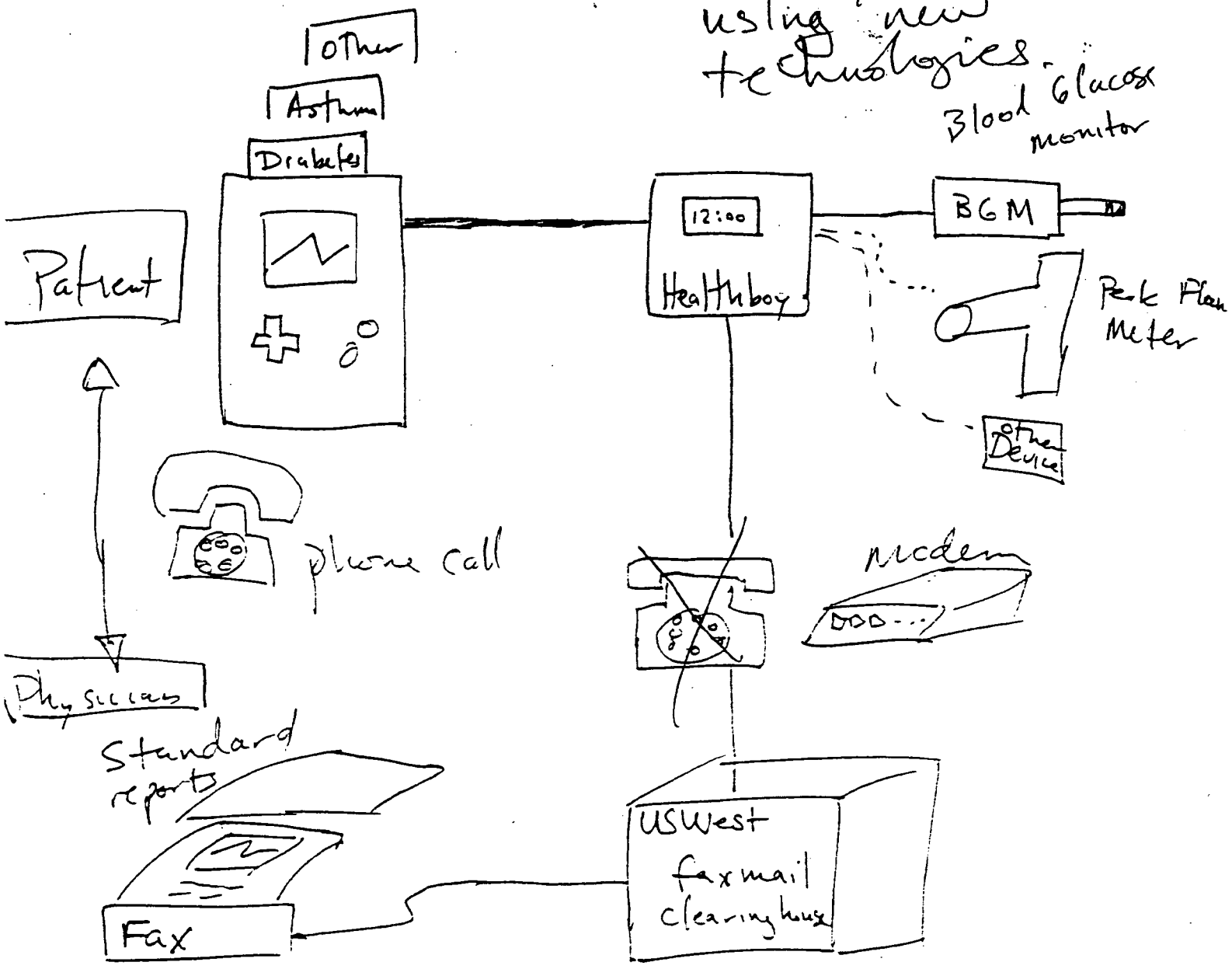
Sincerely,

Steve Brown
President

raya system

Raya Systems, Inc.
2570 West El Camino Real
Suite 309
Mountain View, CA 94040
phone: (415) 949-3933
fax: (415) 949-3935

The System — Link Juvenile Patients to Physicians using new technologies.



CHRISTENSEN, O'CONNOR,
JOHNSON & KINDNESS
2800 Pacific First Centre
1420 Fifth Avenue
Seattle, WA 98101
(206) 682-8100

RAYA SYSTEMS, INC.
\
2570 WEST EL CAMINO REAL
SUITE 309
MT. VIEW, CA 94040

OCTOBER 31 1992

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nvoice # 632084

or Services And Disbursements
**** RAYA-6631
1>MODULAR MICROPROCESSOR...
US PATENT APP

Services

OCT 01 92 JWA	Work on patent application	6.80		1,496.00
OCT 02 92 JWA	Review S. Brown comments regarding patent application draft; Review and revise patent application	1.40		308.00
OCT 07 92 JWA	Meeting with S. Brown; Work on patent application	4.90		1,078.00
OCT 27 92 JWA	Review and revise patent application	2.30		506.00
OCT 28 92 JWA	Review and revise patent application	1.50		330.00
OCT 29 92 JWA	Review and revise patent application	1.50		330.00
OCT 29 92 JM	Work on patent drawings	1.30		65.00
	Total Hours	19.70		
	Total Fees			4,113.00

Disbursements

OCT 19 92 FIRM	Telecopier handling charge	2.00	
	Photocopies	9.30	
	Long distance telephone charges	6.96	
	Total Disbursements		18.26

nable James W	JWA	PTNR	18.40	220.00	4,048.00
lez Joel	JM	ILLU	1.30	50.00	65.00
		ILLU	1.30	50.00	65.00
		PTNR	18.40	220.00	4,048.00

Disbursements

Continued

CHRISTENSEN, O'CONNOR,
JOHNSON & KINDNESS
2800 Pacific First Centre
1420 Fifth Avenue
Seattle, WA 98101
(206) 682-8100

RAYA SYSTEMS, INC. NOVEMBER 30 1992
\
2570 WEST EL CAMINO REAL
SUITE 309
MT. VIEW, CA 94040

:nvoice # 636008

:or Services And Disbursements
'**** RAYA-6631
1>MODULAR MICROPROCESSOR...
US PATENT APP SN 977,323 11/17/92
BROWN SJ

Services

NOV 05 92 JM	Work on patent drawings	.40		20.00
NOV 17 92 JM	Work on patent drawings	.60		51.00
	Total Hours	1.00		
	Total Fees			71.00

Disbursements

NOV 11 92 FIRM	Telecopier handling charge	5.00	
	Long distance telephone charges	.47	
	Total Disbursements		5.47

lez Joel	JM	ILLU	1.00	71.00	71.00	
		ILLU	1.00	71.00	71.00	

Disbursements

	Long distance telephone charges	.47	
	Telecopier handling charge	5.00	
	Total Hours	1.00	
	Total Fees		71.00
	Total Disbursements		5.47
			$76.47

:nvoice due upon receipt. Interest charged at 1.50% per month from invoice date on amounts unpaid 45 days after invoice date.
:hristensen, O'Connor, Johnson & Kindness--Tax I.D. No. 91-0860813
)005

X. RELATED PROCEEDINGS APPENDIX

None.